Radical™

Signal Extraction Pulse Oximeter

OPERATOR'S MANUAL

The Radical Operating Instructions are intended to provide the necessary information for proper operation of all models of the Radical pulse oximetry system. There may be information provided in this manual that is not relevant for your system.

General knowledge of pulse oximetry and an understanding of the features and functions of the Radical Pulse Oximeter are a prerequisite for proper use.

Do not operate the Radical Pulse Oximeter without completely reading and understanding these instructions.

NOTICE

Purchase or possession of this device does not carry any express or implied license to use this device with replacement parts which would, alone or in combination with this device, fall within the scope of one of the patents relating to this device.

CAUTION:

FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

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MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 2601-1/CAN/CSA C22.2 No. 601.1

USA Patents 5337744, 5452717, 5482036, 5490505, 5638818, 5645440, 5758644 and 5782757 and international equivalents. Other patents pending.
Manufactured in USA

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SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES

The Radical Signal Extraction Pulse Oximeter is designed to minimize the possibility of hazards from errors in the software program by following sound engineering design processes, Risk Analysis and Software Validation.

- Explosion hazard. Do not use the pulse oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- The pulse oximeter is NOT intended for use as an apnea monitor.
- A pulse oximeter should be considered an early warning device. As a trend towards patient hypoxemia is indicated, blood samples should be analyzed by laboratory instruments to completely understand the patient's condition.
- The pulse oximeter is to be operated by qualified personnel only. This manual, accessory directions for use, all precautionary information, and specifications should be read before use.
- Electric shock hazard. Do not open the pulse oximeter cover except to replace the battery of the Handheld unit. Only a qualified operator may perform maintenance procedures specifically described in this manual. Refer servicing to Masimo for repair of this equipment.
- As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
- Do not place the pulse oximeter or accessories in any position that might cause it to fall on the patient. Do not lift the pulse oximeter by the power cord or any other cable.
- Interfering Substances: Carboxyhemoglobin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.
- Severe anemia may cause erroneous SpO_2 readings.
- Do not use the pulse oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The pulse oximeter may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.
- For home use, ensure that the pulse oximeter's alarm can be heard from other rooms in the house especially when noisy appliances such as vacuum cleaners, dishwashers, clothes dryers, televisions, or radios are being used.
- Always remove the sensor from the patient and completely disconnect the patient from the pulse oximeter before bathing the patient.
- Do not place the pulse oximeter where the controls can be changed by the patient.
- Do not place the pulse oximeter face against a surface. This will cause the alarm to be muffled.
- Do not place the pulse oximeter on electrical equipment that may affect the pulse oximeter, preventing it from working properly.
- Do not expose the pulse oximeter to excessive moisture such as direct exposure to rain. Excessive moisture can cause the pulse oximeter to perform inaccurately or fail.
- Do not place containers containing liquids on or near the pulse oximeter. Liquids spilled on the pulse oximeter may cause it to perform inaccurately or fail.
- Failure of Operation - If the pulse oximeter fails any part of the setup procedures or leakage tests, remove the pulse oximeter from operation until qualified service personnel have corrected the situation.
- Patient Safety - If a sensor is damaged in any way, discontinue use immediately.

SAFETY INFORMATION, WARNINGS, CAUTIONS AND NOTES (CONTINUED)

- The pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.
- This equipment has been tested and found to comply with the limits for medical devices to the IEC 601-1-2:1994, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
  - Reorient or relocate the receiving device.
  - Increase the separation between the equipment.
  - Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
  - Consult the manufacturer for help.

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about this manual

This manual explains how to set up and use the Radical Pulse Oximeter. Important safety information relating to general use of the Radical Pulse Oximeter appears before this introduction. Other important safety information is located throughout the manual where appropriate.

Read the entire safety information section before you operate the monitor.

In addition to the safety section, this manual includes the following sections:

SECTION 1 OVERVIEW gives a general description of pulse oximetry.

SECTION 2 SYSTEM DESCRIPTION describes the Radical Pulse Oximeter system and its functions and features.

SECTION 3 SETUP describes how to setup the Radical Pulse Oximeter for use.

SECTION 4 OPERATION describes the operation of the Radical Pulse Oximetry system.

SECTION 5 ALARMS AND MESSAGES describes the alarm system messages.

SECTION 6 TROUBLESHOOTING gives troubleshooting information.

SECTION 7 SPECIFICATIONS gives the detailed specifications of the Radical Pulse Oximeter.

SECTION 8 SENSORS AND PATIENT CABLES outlines how to use and care for the Masimo SET LNOP sensors and Masimo SET patient cables.

SECTION 9 SERVICE AND MAINTENANCE describes how to maintain, service and obtain repair for the Radical Pulse Oximeter.

SECTION 10 ACCESSORIES gives you a list of available Radical accessories.

warnings, cautions and notes

Please read and follow any warnings, cautions and notes presented throughout this manual. An explanation of these labels are as follows:

A **WARNING** is provided when actions may result in a serious outcome (i.e., injury, serious adverse affect, death) to the patient or user. Look for text in a gray shaded box.

Sample of Warning:

> **WARNING:** THIS IS A SAMPLE OF A WARNING STATEMENT.

A **CAUTION** is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device or damage to other property.

Sample of Caution:

CAUTION: THIS IS A SAMPLE OF A CAUTION STATEMENT.

A ***NOTE*** is provided when extra general information is applicable.

Sample of Note:

NOTE: *This is a sample of a Note.*

product description

The Radical Pulse Oximeter is a noninvasive, arterial oxygen saturation and pulse rate monitor. Radical can be used as either a Handheld or a Standalone monitor. Radical features a backlit Liquid Crystal Display (LCD) that continuously displays numeric values for SpO_2, pulse rate, plethysmographic waveform and Signal Identification and Quality Indicator (Signal IQ™). Radical can be used to interface with a multiparameter patient monitor to provide Masimo SET pulse oximetry information to that monitor for display.

FEATURES AND BENEFITS

- Clinically proven Masimo SET technology performance
- Applicable for use on neonate, pediatric and adult patients
- Proven for accurate monitoring in motion and low perfusion environments
- Universal application: Handheld, Standalone and Patient Monitor Interface
- Automatic upright display with RadicalScreen™
- Signal IQ™ for signal identification and quality indication
- Analog output and nurse call
- SpO_2, pulse rate, alarm, perfusion index, trend, and pleth waveform displays
- Lightweight design
- Internal batteries for transport:

  Standalone -12 hours (optional)
  Handheld - 4 hours
- Serial output to printers and PCs

INDICATIONS FOR USE

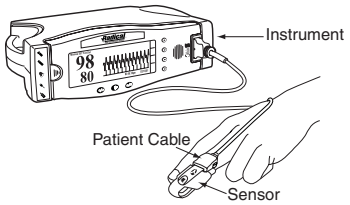
The Radical Pulse Oximeter and accessories are indicated for the continuous, noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Radical Pulse Oximeter and accessories are indicated for use with adult, pediatric and neonatal patients during both motion and no motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile and home environments. In addition, the Radical Pulse Oximeter is indicated to provide continuous noninvasive monitoring data, obtained from the Radical Pulse Oximeter, to validated multiparameter patient monitors* for display on those monitors.

*Contact Masimo for the latest list of SatShare validated multiparameter monitors.

pulse oximetry

GENERAL DESCRIPTION

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor is connected to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in three ways: 1) as a percent value for arterial oxygen saturation (SpO_2), 2) as a pulse rate (PR) and 3) as a plethysmographic waveform. The following figure shows the general monitoring setup.

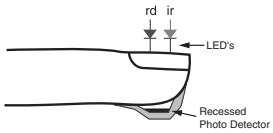


PRINCIPLE OF OPERATION

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood) and deoxyhemoglobin (non-oxygenated blood) differ in their absorption of red and infrared light (spectrophotometry).
2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Radical Pulse Oximeter uses a two-wavelength pulsatile system to distinguish between oxygenated and deoxygenated blood. Signal data is obtained by passing red (rd) (660 nm wavelength) and infrared (ir)(905 nm wavelength) light through a capillary bed (for example a fingertip, a hand, a foot) and measuring changes in light absorption during the pulsatile cycle. See figure below. The Radical utilizes a sensor with red and infrared light-emitting diodes (LEDs) that pass light through the site to a photodiode (photodetector). The photodetector receives the light, converts it into an electronic signal and sends it, via a patient cable, to the Radical for calculation.



Once Radical receives the signal from the patient sensor, it utilizes Masimo SET signal extraction technology for calculation of the patient's functional oxygen saturation and pulse rate.

FUNCTIONAL VS. FRACTIONAL SATURATION

The Radical measures and displays functional saturation: the amount of oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. The Radical does not measure fractional saturation: oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin such as carboxyhemoglobin or methemoglobin. To convert fractional saturation to functional saturation, the fractional saturation measurements must be converted according to:

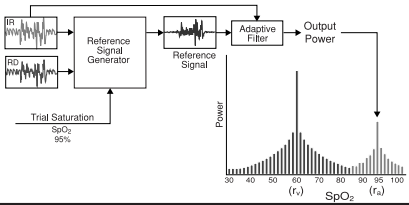
$$\text{Functional saturation} = \frac{\text{Fractional saturation}}{100 - (\%\ \text{carboxyhemoglobin} + \%\ \text{methemoglobin})} \times 100$$

MEASURED VS. CALCULATED SATURATION

Oxygen saturation measurements obtained from a pulse oximeter are commonly compared to saturations calculated from the partial pressure of oxygen (PO_2) obtained from an arterial blood gas sample. When comparing the two measurements, caution should be used when interpreting the values, as the calculated value obtained from the blood gas sample may differ from the SpO_2 measurement of the pulse oximeter. Different results are usually obtained from the blood gas sample if the calculated saturation is not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation, such as: pH, temperature, the partial pressure of carbon dioxide (PCO_2), 2,3-DPG, and fetal hemoglobin. Also, as blood gas samples are usually taken over a period of 20 seconds (the time it takes to draw blood) a meaningful comparison can only be achieved if the core oxygen saturation of the patient is stable and not changing over the period of time that the blood gas sample is taken.

MASIMO SET SIGNAL EXTRACTION TECHNOLOGY

Masimo Signal Extraction Technology's signal processing differs from conventional pulse oximeters. Conventional pulse oximeters assume that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, however, the non-arterial blood also moves, which causes conventional pulse oximeters to read low values, because they cannot distinguish between the arterial and venous blood movement (sometimes referred to as noise). Masimo SET pulse oximetry utilizes adaptive digital filtering. Adaptive filters are powerful because they are able to adapt to the varying physiologic signals and/or noise and separate them by looking at the whole signal and breaking it down to its fundamental components. Masimo SET signal processing algorithm, Discrete Saturation Transform™ (DST), reliably identifies the noise, isolates it and, using adaptive filters, cancels it. It then reports the true arterial oxygen saturation for display on the monitor.

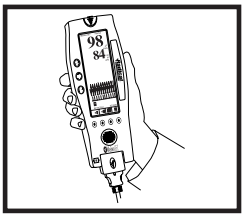


Masimo SET DST

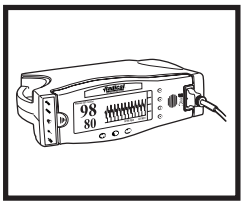
introduction

Radical provides the functionality of three pulse oximeters in one:

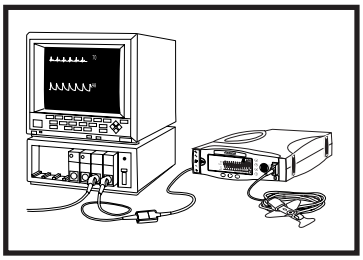
- Radical is a fully featured Handheld pulse oximeter
- Radical is a fully featured standalone pulse oximeter
- Radical interfaces to the SpO_2 input module of multiparameter patient monitors* to upgrade conventional pulse oximetry technology to Masimo SET technology.



The Handheld portion of Radical contains the majority of the pulse oximeter features. All pulse oximetry measurement information, as well as device status data is displayed on the Handheld LCD screen. All user input is handled through the control buttons on the front panel. The sensor cable connector is located on the Radical Handheld oximeter.



The Handheld oximeter snaps into the Radical Docking Station to provide a fully featured standalone pulse oximeter. The Docking Station connects to AC power for standalone operation or charging of the Handheld an optional Docking Station battery is available. The standalone Radical features nurse call, analog output and interfaces to serial printers.



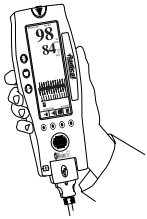
Utilizing a SatShare™ cable, the standalone Radical also interfaces with the SpO_2 input of a validated multiparameter patient monitor*, instantly upgrading the conventional pulse oximetry to Masimo SET pulse oximetry. The SatShare cable attaches to the back of the Radical Docking Station, and SatShare cables are available to interface with most multiparameter patient monitors*.

CAUTIONS:

- THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL. REFER TO THE RADICAL DISPLAY FOR PATIENT WAVEFORM.
- IF DISPLAYING THE SIMULATED WAVEFORM IS NOT DESIRABLE, IT IS RECOMMENDED TO TURN OFF THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR

*Contact Masimo for the latest list of SatShare validated multiparameter monitors.

radical handheld

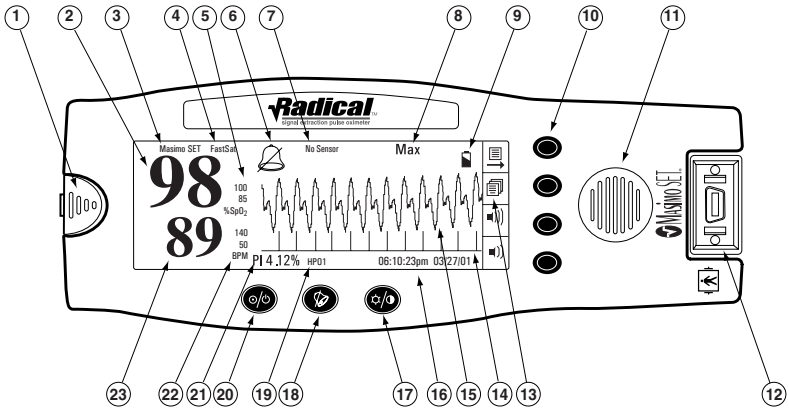


The Handheld Radical provides most of the functionality of the pulse oximeter. All user input and displays are controlled by this part of the Radical system. The sensor cable connects into the swivel connector on the Handheld unit. The Handheld is battery powered and can be used either as a transport monitor or as a Handheld Pulse Oximeter for spot checks.

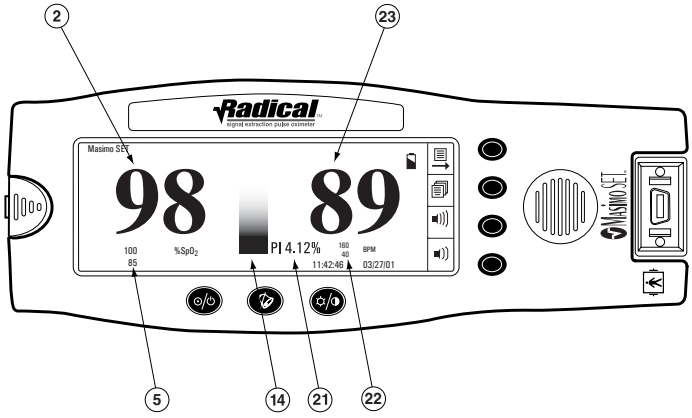
HANDHELD FRONT PANEL

The following figure and corresponding text outline all the features of the Handheld Radical:

Pleth + Signal IQ View



Numbers View

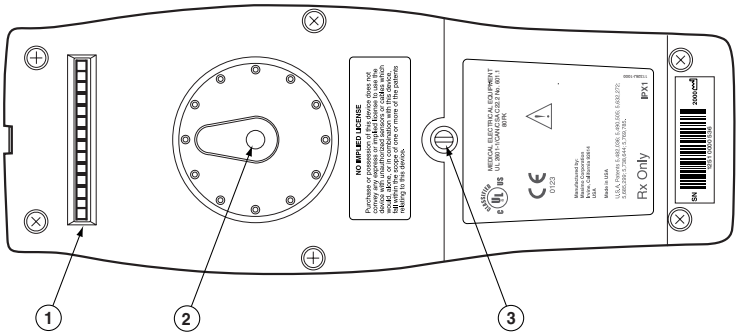


①		**Handheld Release Button**	Press down the Handheld Release Button and pull the Handheld device off the Docking Station.
②	98	**SpO_2 Measurement Display**	The functional arterial hemoglobin oxygen saturation is displayed in units of percentage SpO_2. The upper and lower SpO_2 alarm limits are also displayed next to the SpO_2 measurement. When a sensor is not connected to a patient and during pulse search, the display will show dashed lines. When the measured value is outside of the alarm limits, the SpO_2 Measurement Display flashes and an alarm will sound. The oxygen saturation is calculated and the display is updated at a frequency of once per second.
③	Masimo SET	**Masimo SET**	The Masimo SET symbol is shown on the Radical display when SET processing is active.
④	FastSat	**FastSat**	The FastSat symbol is shown on the Radical display whenever the Radical is set to operate in the FastSat mode.
⑤	100 85	**Saturation Alarm Limits Display**	The Saturation Alarm Limits Display shows the upper and lower saturation alarm limits. When an alarm limit is reached or exceeded, the SpO_2 value and the violated limit flashes.
⑥		**Alarm Status Indicator**	The alarm status indicator (a bell) can be shown with or without a slash. It flashes when an alarm condition is present. When the alarm is silenced using the Alarm Silence Button, an alarm status indicator with a slash and a timer is shown to indicate that the alarm is temporarily silenced. When the alarm is silenced through All Mute menu selection, which is permanent until power is cycled or deselected using menu, an alarm status indicator with a slash is shown to indicate that alarm has been silenced.
⑦	No Sensor	**System Message Area**	The system messages generated by the instrument are displayed in the System Message Area. See Section 5, System Messages.
⑧	Max	**Maximum Sensitivity**	The Maximum Sensitivity icon is shown on the Radical display whenever the Radical is set to operate in the Maximum sensitivity mode.
⑨		**Battery Status Indicators**	The Battery Status Indicators show the capacity of the Radical Handheld and optional Docking Station batteries. The indicator flashes when less than 15 minutes of battery life is left and the battery needs to be recharged. The Docking Station Battery Status indicator is not shown when the optional Docking Station battery is not present.
⑩		**Touch Key Control Buttons**	Press a Touch Key Control Button to select the corresponding touch key icon. See Section 4, Touch Key Control Buttons and Icons for more details.
⑪		**Loudspeaker**	The loudspeaker indicates audio alarms. Care should be taken not to cover the loudspeaker and muffle the audible alarm volume.
⑫		**Patient Cable Connector**	Connect the patient cable to the Handheld Radical by plugging the cable into the Patient Cable Connector. Use only Masimo compatible sensors and cables with this oximeter. See Section 8, Sensors and Patient Cables for more details.
⑬		**Touch Key Icons**	The Touch Key Icons indicate the software menu items that can be selected through the Touch Key Control Buttons. Pressing a Touch Key Control Button next to an icon selects the option.
⑭		**Signal IQ**	The Signal IQ shows the acquired signal quality and the timing of the pulse. A tall vertical line indicates a high quality signal, while a small vertical line indicates a low quality signal. The Signal IQ waveform display is updated with a frequency of 31.25 times per second. The Signal IQ may also be shown as a single, pulsating bar.

⑮	**Pulse Waveform Display**	The Pulse Waveform Display shows the acquired plethysmograph waveform. The pleth waveform is scaled with signal strength. Signal strength is defined as the relation of arterial pulsatile signal to the non-pulsatile signal component. The Pulse Waveform Display is updated with a frequency of 31.25 times per second.
⑯ 06:10:23pm 03/27/01	**Time and Date Indicator**	The Time and Date Indicator displays the current time and date. The date and time is displayed in dd/mm/yyyy or mm/dd/yyyy format. Select the date and time display format in the Clock menu.
⑰	**Backlight/ Contrast Button**	Press the Backlight Button to change the illumination level of the backlight. With the AC line power connected, four levels of illumination are available (in addition to the no illumination level). In the Handheld mode, three levels of illumination are available (again in addition to the no illumination level). Use the lowest illumination for most efficient battery usage. The backlight Button is also used to change the contrast of the LCD display. Press and hold the Backlight Button for longer than two seconds to change the contrast. Release the Backlight Button at the desired contrast setting.
⑱	**Alarm Silence Button**	Press the Alarm Silence Button to temporarily silence patient alarms. Press the Alarm Silence Button when the SENSOR OFF or NO SENSOR messages are flashing (i.e. the sensor is removed from the patient) to acknowledge the end of monitoring. In these states, all further alarms are suspended until the pulse oximeter starts measuring SpO_2 and pulse rate again. ***Note:*** *System failure alarms can be silenced by pressing the Power/Standby or Alarm Silence Button. If the Power/Standby button does not silence the system fault alarm, press the alarm silence button.*
⑲ HP01	**Output Mode Indicator**	The Output Mode Indicator displays the output mode selected by the user. The Output Mode Indicator also displays the type of SatShare™ cable. The Output Mode indicator is only displayed when the Radical device actively outputs data other than ASCII text, or interfaces with a monitor through the SatShare cable.
⑳	**Power/Standby Button**	Press the Power/Standby Button to turn the instrument on. Press, hold the button for more than 2 seconds and then release the button to turn the instrument off.
㉑ PI	**Perfusion Index**	The Perfusion Index indicates numerically the percentage of pulsatile signal to non-pulsatile signal.
㉒ 140 50	**Pulse Rate Alarm Limits Display**	The Pulse Rate Alarm Limits Display shows the upper and lower pulse rate alarm limits. When an alarm limit is reached or exceeded, the pulse rate value and the violated limit flashes.
㉓ **89**	**Pulse Rate Measurement Display**	The Pulse Rate Measurement Display shows the patient's pulse rate in beats per minute. The upper and lower pulse rate alarm limits are also displayed next to the pulse rate measurement. The pulse rate is calculated and the display is updated at a frequency of once per second.

HANDHELD BACK PANEL

The Handheld back panel features the interconnection to the Docking Station, an accessory mount for the pole clamp accessory and access to the Handheld battery pack.



①	**Docking Station Connector**	The Radical Handheld interfaces with the Docking Station through this connector.
②	**Pole Clamp Accessory Holder**	The optional Pole Clamp accessory attaches to this holder. See the Directions for Use of the Pole Clamp accessories for attachment instructions.
③	**Battery Cover**	The Radical Handheld is powered by a NiMH battery located in this compartment. For battery care and replacement please see Section 9, Replacing the Batteries.

radical standalone

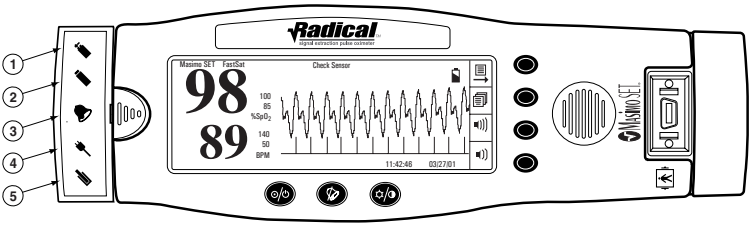
When the Radical Handheld is placed into the Docking Station, the Radical becomes a full-featured standalone device. The Radical Standalone acts as a battery charger for the Handheld device and has AC power connection capabilities. The Standalone can also interface to serial devices, nurse call or analog output devices, and multiparameter patient monitors through a SatShare cable.

There are several models of Docking Stations available. The following table outline which features are available for each model of Docking Station.

DOCKING STATION FEATURES	RDS-1	RDS-1B	RDS-2	RDS-3	RDS-3B
AC Power Input	■	■	■	■	■
SatShare Interface	■	■			
Serial RS-232 Interface	■	■		■	■
Nurse Call/Analog Output Interface	■	■		■	■
12-hour Extended Battery		■			■
Automatic Display Rotation Support (Gravity Detector)	■	■		■	■
Docking Station Battery Charging Indicator	■	■		■	■
Handheld Battery Charging Indicator	■	■	■	■	■
Red Alarm Inidcator	■	■		■	■
AC Power Indicator	■	■	■	■	■
Docking Indicator	■	■		■	■

STANDALONE FRONT PANEL

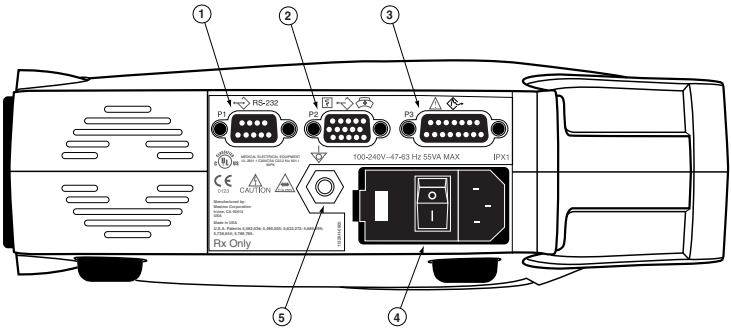
The following figure and corresponding text review the features of the Radical Standalone device.



①	**Docking Station Battery Charging Indicator**	The Docking Station Battery Charging Indicator is illuminated when the Docking Station battery is charging. The indicator blinks just prior to charging. The charging indicator does not illuminate when the battery is fully charged or when the battery is not present.
②	**Handheld Battery Charging Indicator**	The Handheld Battery Charging Indicator is illuminated when the Handheld battery is charging. The indicator blinks just prior to charging. The Charging Indicator does not illuminate when the battery is fully charged or when the battery is not present.
③	**Visual Alarm Indicator**	The Visual Alarm Indicator is illuminated when an alarm condition is active and the Alarm Status Indicator is shown.
④	**AC Power Indicator**	The AC Power Indicator is illuminated when the Radical Docking Station is plugged into AC line power.
⑤	**Docking Indicator**	The Docking Indicator is illuminated when the Handheld unit is turned on and is properly interfaced to a Docking Station.

NOTE: *When the Radical Standalone is turned on, all indicator LEDs initially turn on and off at start up.*

STANDALONE BACK PANEL



① **P1** **Serial Output Connector**

RS-232

Use the Serial Output Connector to connect a serial device, including a serial printer or PC, to the Radical. The data is provided in standard RS-232C format. See Section 7, Serial Interface Specifications. All external device connections to the Serial Output Connector must be IEC-60950 compliant.

② **P2** **Analog Output / Nurse Call Connector**

Use the Analog Output Connector to interface with an analog output device, such as a chart recorder or nurse call system. All external device connections to the Analog Output / Nurse Call Connector must be IEC-60950 compliant.

③ **P3** **SatShare Cable Connector**

Use the SatShare Cable Connector to connect a SatShare cable to the SpO_2 input connector of a multiparameter patient monitor. All external device connections to the SatShare Cable Connector must be IEC-60101-1-1 compliant. SatShare cables are available to interface with most major multiparameter patient monitors. Check the label on the SatShare cable and the SatShare Directions for Use to ensure that the correct cable is used for each type of patient monitor. Refer to the Masimo web site at www.masimo.com for the latest SatShare cables and validated instruments.

④ **Power Entry Module**

The power entry module contains the input connector for AC power, an on/off switch and two fuses. The AC input and the on/off switch provide power to the system from the AC line. Always connect the pulse oximeter to the mains power for continuous operation and/or battery recharging.

NOTE: *Some power entry modules may not have the on/off switch.*

⑤ **Equipotential Ground Connector**

Use the Equipotential Ground Connector for grounding.

SYMBOLS

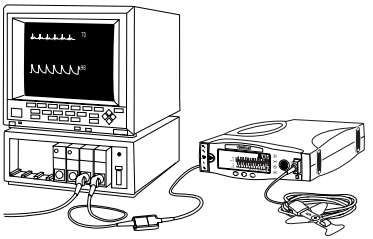
The following symbols are found on the back of the Radical Docking Station, they are defined below:

SYMBOLS	
RS-232	RS-232
SatShare interface	
Equipotential Ground Terminal	
See Instructions for Use	
Fuse Replacement	T1A 250V
Analog Out Interface	
Nurse Call Interface	

NOTE: *Some of the interfaces and symbols are not available in all versions of the Docking Station.*

radical monitor interface

In addition to being a full-featured Handheld and Standalone Pulse Oximeter, Radical's unique SatShare interface links the Radical to most existing multiparameter patient monitors through the pulse oximetry patient cable or SpO_2 input connector.



- Upgrades any approved and validated monitor to Masimo SET performance by using the calculated SpO_2 and pulse rate determined by Radical to simulate an ideal waveform, which is sent to the validated multiparameter patient monitor.
- Connects into the SpO_2 patient cable or SpO_2 input connector of the multiparameter patient monitor.

CAUTION: THE WAVEFORM DISPLAYED ON THE MULTIPARAMETER PATIENT MONITOR IS A SIMULATED SIGNAL. REFER TO THE RADICAL DISPLAY FOR THE PATIENT WAVEFORM.

introduction

Before the Radical Pulse Oximeter can be used in a clinical setting, it needs to be inspected, properly setup and the batteries need to be fully charged.

unpacking and inspection

Remove the instrument from the shipping carton and examine for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.

If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in Section 9, Service and Repair.

preparation for monitoring

The following sections of the manual describe the preparation, set-up and initial installation of the Radical Pulse Oximeter.

RADICAL POWER REQUIREMENTS

Always use a hospital grade, AC power cable to connect the Radical Pulse Oximeter to an AC power source. Do not connect the Radical Pulse Oximeter Docking Station to an AC outlet controlled by a switch.

Verify the AC power voltage and frequency before use. Verify that the power source can provide adequate power rating as indicated on the rear panel of the Radical Docking Station.

The Radical Pulse Oximeter is designed to operate on 100 to 240VAC, 47-63 Hz. The device is rated at 55 VA max.

Connect a hospital grade power cable to the power entry module of the Radical unit (IEC-320 connector type at the Radical). Connect the power cable to an AC power source.

Turn the AC power switch of the power entry module of the Docking Station to " | "*. Ensure that the unit is adequately powered by verifying that the AC power indicator on the Docking Station is illuminated.

***NOTE:** Some power entry modules may not have the AC power switch.*

CAUTION:

- CONNECT THE OXIMETER ONLY TO A HOSPITAL-GRADE RECEPTACLE.
- DO NOT UNDER ANY CIRCUMSTANCES REMOVE THE GROUNDING CONDUCTOR FROM THE POWER PLUG.
- DO NOT USE EXTENSION CORDS OR ADAPTERS OF ANY TYPE. THE POWER CORD AND PLUG MUST BE INTACT AND UNDAMAGED.

- IF THERE IS ANY DOUBT ABOUT THE INTEGRITY OF THE PROTECTIVE EARTH CONDUCTOR ARRANGEMENT, OPERATE THE OXIMETER ON INTERNAL BATTERY POWER UNTIL THE AC POWER SUPPLY PROTECTIVE CONDUCTOR IS FULLY FUNCTIONAL.
- TO ENSURE PATIENT ELECTRICAL ISOLATION, CONNECT ONLY TO OTHER EQUIPMENT WITH ELECTRICALLY ISOLATED CIRCUITS.
- DO NOT CONNECT TO AN ELECTRICAL OUTLET CONTROLLED BY A WALL SWITCH OR DIMMER.

INITIAL BATTERY CHARGING

Before use, the Radical Handheld battery and the optional Docking Station battery needs to be fully charged.

To charge the batteries, attach the Handheld unit to the Docking Station, turn the AC power switch to " I "*. Verify that the batteries are charging. The battery charging LED indicators on the Docking Station flash prior to charging and remain illuminated while the batteries are charging.

Refer to Section 9, Battery Operation and Maintenance, for proper battery charging.

Note: *Some power entry modules may not have the AC power switch.*

INITIAL INSTALLATION

Place the Docking Station on a stable hard flat surface near the patient. Always place the Radical unit on a dry surface. Maintain a minimum of 3 cm (1 inch) free space around the Radical Standalone unit. Make sure that Radical loudspeaker is not covered to avoid a muffled alarm sound.

The Radical Handheld, Docking Station or Standalone should not be operated outside the following environmental conditions:

OPERATING ENVIRONMENTAL CONDITIONS	
TEMPERATURE	+5°C to +40°C, +41°F to +104°F
HUMIDITY	5% to 95%, non-condensing
OPERATING ALTITUDE	1060 mbar to 500 mbar pressure -1000 ft to 18,000 ft (-304 m to 5,486 m)

monitor setup

The Radical Pulse Oximeter stores two types of default values: those that Radical automatically reverts to after a power cycle, and those that can be changed by the user and will be remembered after a power cycle.

The following table outlines the default values that Radical reverts to after a power cycle.

OPTION	DEFAULT SETTING
ALARM SILENCE	Alarm silence time is set to 120 seconds
LCD SCREEN ILLUMINATION (AC power)	Illumination set to maximum, level 4
LCD SCREEN ILLUMINATION (battery power)	Illumination set to off

The following table outlines the type of settings that the user can change and Radical will remember after a power cycle.

OPTION	DEFAULT SETTING
SpO_2 HIGH/LOW ALARM LIMIT	Set to pre-power down setting
PULSE RATE HIGH/LOW ALARM LIMIT	Set to pre-power down setting
DISPLAY VIEW AND CONTRAST	Set to pre-power down setting
AVERAGING TIME	Set to pre-power down setting
FASTSAT	Set to pre-power down setting
HOME USE	Set to pre-power down setting
INTERFACE ALARMS	Set to pre-power down setting
SATSHARE NUMBERS	Set to pre-power down setting
POWER SAVE	Set to pre-power down setting
SENSITIVITY	Set to pre-power down setting
DATE AND TIME FORMAT	Set to pre-power down setting
LANGUAGE	Set to pre-power down setting
ANALOG OUTPUT	Set to pre-power down setting
SERIAL OUTPUT PORT MODE	Set to pre-power down setting

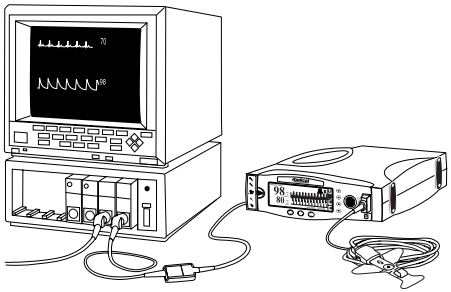
ALARM VOLUME	Set to pre-power down setting
PULSE BEEP VOLUME	Set to pre-power down setting
TREND DISPLAY PARAMETERS	Set to pre-power down setting
TREND PERIOD	Set to pre-power down setting

satshare setup

The Radical Pulse Oximeter has been proven to be accurate during patient motion and low perfusion conditions. Saturation and pulse rate values from the Radical may be displayed on a multiparameter monitor through the SatShare feature.

The SatShare feature provides an ideal, simulated waveform corresponding to the measured saturation and pulse rate values determined by the Masimo SET technology. This waveform may be used to display these values on multiparameter monitors through the multiparameter monitor's oximetry sensor or input connector.

It is recommended that the Radical is positioned close to the multiparameter monitor with the Radical screen visibly displaying the plethysmographic waveform and the saturation and pulse rate measurements.



SatShare Setup:

1. Select the SatShare cable that is appropriate for the multiparameter monitor that is being connected. Check the Masimo web site at www.masimo.com for the latest list of available SatShare cables and validated instruments.
2. Connect the labeled end of the cable to the SatShare Cable Connector port on the back of the Docking Station. Tighten the connector screws for a secure connection.
3. Connect the other end of the SatShare cable either to the sensor connector of the multiparameter monitor's SpO_2 cable or directly to the SpO_2 connector on the monitor.

4. Verify that Radical recognizes the correct cable. The name of the SatShare cable will be displayed on the LCD screen when the SatShare mode is functional.
5. Set the multiparameter monitor's high and low saturation and pulse rate alarm limits as appropriate.
6. Set the multiparameter monitor's averaging time to the lowest setting (i.e. fastest response). Radical's ideal waveform obviates the need for additional averaging by the monitor. If the multiparameter monitor's averaging time is not changed, the time to display physiological changes in saturation on the monitor will be increased with SatShare. However, the delay can be minimized by reducing the multiparameter monitor's averaging time.
7. While in the SatShare mode, if there are any significant discrepancies between the readings from the Radical and those on the monitor displaying the values obtained from SatShare, the values reported by the Radical are to be considered the correct values.
8. To use the Radical with SatShare while it is not connected to AC power, set the Power Save parameter in the General menu to "No", refer to Section 4, Operation. Please note that if the Radical is used in this mode, the length of time the Radical can operate on battery power will be significantly diminished.
9. Set the SatShare Numbers and the Interface Alarms parameters in the General menu according to Customer preference.
10. If displaying the simulated waveform is not desirable, it is recommended to turn off the pleth waveform display of the multiparameter patient monitor.

CAUTIONS:

- WHILE OPERATING IN SATSHARE MODE, THE AUDIBLE ALARMS MAY BE DISABLED ON THE RADICAL. USE THE ALARM SETTINGS OF THE MULTIPARAMETER MONITOR FOR AUDIBLE AND VISUAL ALARM INDICATION.
- TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SATSHARE CONNECTOR UNLESS THE RADICAL PULSE OXIMETER IS CONNECTED TO THE AC MAIN POWER SUPPLY.
- TO ENSURE THAT THE SAFETY LEVEL DURING DEFIBRILLATION IS MAINTAINED, MAKE SURE THAT THE SATSHARE CABLE CONNECTOR IS PROPERLY SECURED AT THE DOCKING STATION.

WARNING: EXTERNAL DEVICE CONNECTIONS TO THE SATSHARE PORT MUST BE IEC-60101-1-1 COMPLIANT.

hp vuelink setup

1. Select the HP VueLink selection from the Output menu on the Radical. Refer to Section 4, Output.
2. Connect one end of the VueLink cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the VueLink cable to the VueLink module and insert the module into the HP/Agilent monitor rack.
4. The SpO_2 and pulse rate values will automatically appear on the HP/Agilent monitor.
5. In order for the pleth waveform to be displayed on the HP/Agilent monitor and for the HP/Agilent monitor to indicate the alarm conditions measured by the pulse oximeter, the user must configure the HP/Agilent monitor. Please see the HP/Agilent Operator's manual for complete instructions.
6. The Radical Pulse Oximeter can be set up to audibly indicate all patient alarms while communicating with the HP VueLink module. Use the Inteface Alarms setting in the General menu to enable and disable audible alarms on the Radical.

spacelabs universal flexport setup

1. Select the Spacelabs Flexport selection from the Output menu on the Radical.
2. Connect one end of the Spacelabs Flexport cable to the Serial Output connector on the back of the Docking Station.
3. Connect the other end of the Spacelabs Flexport cable to the Spacelabs Universal Flexport connector.
4. The SpO_2 and pulse rate values will automatically appear on the Spacelabs screen.
5. In order for the pleth waveform to be displayed on the Spacelabs screen and for the Spacelabs monitor to indicate the alarm conditions measured by the pulse oximeter, the user must configure the Spacelabs monitor. Please see the Spacelabs monitor Operator's manual for complete instructions.
6. The Radical Pulse Oximeter can be set up to audibly indicate all patient alarms while communicating with the Spacelabs Flexport module. Use the Inteface Alarms setting in the General menu to enable and disable audible alarms on the Radical.

introduction

To operate the Masimo SET Radical Pulse Oximeter effectively, the device must be set up properly, and the operator must:

- Know how the pulse oximeter derives its readings (see Section 1, Pulse Oximetry).
- Be familiar with its controls, components and operation.
- Understand its status and alarm messages (see Section 5, Alarm Identification, System Messages and Section 6, Troubleshooting).

basic operation

GENERAL SETUP AND USE

1. Inspect the oximeter case for damage.
2. Connect the patient cable to the Patient cable connector of the Radical. Make sure it is a firm connection and the cable is not twisted, sliced or frayed.
3. Ensure that the power cord is plugged into the Power Entry Module of the oximeter and into the AC power.
4. Ensure that the AC power switch of the Power Entry Module of the Docking Station is in the " | " position.
   NOTE: *Some power entry modules may not leave the on/off switch.*
5. Select a sensor that is compatible with the oximeter before connecting it to the patient cable. See section 8, Sensors and Patient Cables. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector (white plastic casing) are properly aligned. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor's light source and photodetector.
6. Attach the sensor to the patient. Refer to the Directions for Use of the sensor.
7. Connect the sensor to the patient cable with the logos lining up; make sure it is a firm connection.
8. Press the Power/Standby button to turn the oximeter on.
9. Make sure the display window is free of alarm and system failure messages (see Section 5, Alarm Identification).
10. On the display, verify
    - The high and low alarm limits for SpO_2 and pulse rate.
    - The readings for SpO_2 and pulse rate.

    NOTE: *"—" may appear on the numeric display until the SpO_2 and pulse rate readings have stabilized (approximately 10 seconds).*

11. Verify that the patient alarms are functional by setting the high and low SpO_2 and pulse rate alarm limits beyond the patient readings.

- An alarm tone sounds.
- The violated alarm limit and reading flash on the display.
- The red alarm indicator flashes on the Docking Station (standalone operation).

12. Verify the sensor alarms are functional by removing the sensor from the sensor site.

- SENSOR OFF appears in the message area of the graphic display.
- The alarm tone sounds.
- The alarm indicator flashes.
- Disconnect the sensor from the patient cable or oximeter.
- Confirm that "NO SENSOR" appears in the message area of the graphic display.

13. Verify alarm silence operation.

- Create an alarm condition by lowering the SpO_2 or pulse rate high alarm limits beyond the patient readings.
- Press the Alarm Silence button.
- The alarm tone ceases for the displayed amount of time.

14. To begin patient monitoring:

- Adjust the alarm limits.
- Adjust the alarm volumes.
- Adjust the pulse beep volume.

15. Verify the sensor is on correctly and that the measured data is appropriate, see Section 4, Successful SpO_2 Monitoring.

16. Monitor the patient.

17. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules. See the Directions for Use of the sensor.

18. Press and hold the Power/Standby Button for 2 seconds to turn the oximeter off.

successful SpO_2 monitoring

The following general points will aid in ensuring oximetry monitoring success.

- Place the sensor on a site that has sufficient perfusion and provides proper alignment of the LED's and photodetector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not constrict the monitoring site when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor Directions for Use for proper sensor application.

NUMERIC DISPLAY - SpO_2

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and PR.

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous pulsations at the frequency of the patient's arterial pulse.
- Very low hemoglobin levels.

NUMERIC DISPLAY - PULSE RATE

The Pulse Rate displayed on the Radical may differ slightly from the heart rate displayed on ECG monitors due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the instruments or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can be additive to the pulse rate displayed on the pulse oximeter .

SIGNAL IQ

The Radical display provides a visual, indicator of the plethysmogram signal quality and an alert when the displayed SpO_2 values are not based on adequate signal quality. The signal quality indicator displayed on the Radical is called the Signal IQ. The Signal IQ can be used to identify the occurrence of a patient's pulse and the associated signal quality of the measurement.

With motion, the plethysmographic waveform is often distorted and may be obscured by artifact. The Signal IQ, shown as a vertical line, coincides with the peak of an arterial pulsation. Even with a plethysmographic waveform obscured by artifact, the Radical locates the arterial pulsation. The pulse tone (when enabled) coincides with the vertical line of the Signal IQ.

The height of the vertical line of the Signal IQ indicates the quality of the measured signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. When the signal quality is very low the accuracy of the SpO_2 measurement may be compromised, and a “Low Signal IQ” message is displayed in the message area on the Radical display. When the "Low Signal IQ" message appears proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the Radical to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. For example, as may occur while lifting or crossing their legs, during a diaper change.

After performing the above, if the "Low Signal IQ" message is displayed frequently or continuously obtaining an arterial blood specimen for CO-oximetry analysis may be considered to verify the oxygen saturation value.

LOW PERFUSION

The Radical displays an indicator (i.e., "Low Perfusion" message) when there are very low amplitude arterial pulsations.

It has been suggested that at extremely low perfusion levels, pulse oximeters can measure peripheral saturation, which may differ from central arterial saturation[1]. This "localized hypoxemia" may result from the metabolic demands of other tissues extracting oxygen proximal to the monitoring site under conditions of sustained peripheral hypoperfusion. (This may occur even with a pulse rate that correlates with the ECG heart rate.)

CAUTION: IF THE LOW PERFUSION MESSAGE IS FREQUENTLY DISPLAYED, FIND A BETTER-PERFUSED MONITORING SITE. IN THE INTERIM, ASSESS THE PATIENT AND, IF INDICATED, VERIFY OXYGENATION STATUS THROUGH OTHER MEANS.

[1] Severinghaus JW, Spellman MJ. Pulse Oximeter Failure Thresholds in Hypotension and Vasoconstriction. *Anesthesiology* 1990; 73:532-537

ACTIONS TO BE TAKEN

If the SpO_2 readings show significant differences, do the following:

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10-30% methyl salicylate and 2-10% menthol) for 20-30 seconds. Strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment. If these solutions are not possible, operate the oximeter on battery power, or try plugging the oximeter into a different electrical outlet.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the Radical Pulse Oximeter with integrated Masimo SET technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: IF ANY MEASUREMENT SEEMS QUESTIONABLE, FIRST CHECK THE PATIENT'S VITAL SIGNS BY ALTERNATE MEANS AND THEN CHECK THE PULSE OXIMETER FOR PROPER FUNCTIONING.

touch key control button

touch key control buttons and icons

The touch key control buttons are the four dark grey control buttons to the right of the Handheld display. To select a touch key icon, press and release the dark gray control button to the right of the icon.

On the Radical display, four icons are shown on the right side or bottom of the LCD display.

FIRST PAGE

	Next Menu Page	Press the Next Menu Page button to access the second page of selections.
	Menu Access	Press the Menu Access button to enter the main menu.
	Increase Loudness	Press the Increase Loudness button to increase the volume of the pulse beep. Seven levels of volume exist.
	Decrease Loudness	Press the Decrease Loudness button to decrease the volume of the pulse beep. The lowest volume level will silence the pulse beep.

SECOND PAGE

	Next Menu Page	Press the Next Menu Page button to return to the first page of selections.
	Trend Display	Press the Trend Display button to show the trend data on the display.
	Sensitivity	Press the Sensitivity button to toggle between the Normal and Maximum sensitivity modes. Use the Normal sensitivity setting for normal patient monitoring purposes. Use the Maximum sensitivity setting for improved sensitivity performance on patients with extremely low perfusion. ***Note:*** *When using the Maximum sensitivity setting, the SENSOR OFF detection performance may be compromised.* The device automatically retains the sensitivity setting after a power cycle.
	Rotate Display	Press the Rotate Display button to reconfigure the display screen in a vertical or horizontal format. The display rotates clockwise in 90 degree increments.

navigating the main menu

When the main menu is accessed, the plethysmograph and Signal IQ waveform displays are replaced with the main menu items. The touch key icons, displayed along the right edge of the LCD display, are also replaced by the menu access icons. When the main menu is accessed the monitor remains functional and the saturation and pulse rate numbers will continue to be displayed.

MAIN MENU SELECTION

The top menu category uses the following four menu selections and touch key control buttons and icons.

	EXIT	Select the Exit icon to exit the main menu.
	SELECT CATEGORY	Select the Select Category icon to select the highlighted menu item and enter the next level menu.
	PREVIOUS	Select the Previous icon to scroll through the menu items without selecting them. Once a menu item is highlighted, enter the menu by pressing the Select Category icon.
	NEXT	Select the Next icon to scroll through the menu items without selecting them. Once a menu item is highlighted, enter the menu by pressing the Select Category icon.

MENU CATEGORIES

Once a menu category has been selected, a new set of menu selections and icons are displayed.

	EXIT	Select the Exit icon to exit the menu category and return to the previous menu.
	EDIT PARAMETER	Select the Edit Parameter icon to select the highlighted parameter for editing.
	PREVIOUS	Select the Previous icon to scroll through the parameters without selecting them. Once a parameter is highlighted, edit the parameter by pressing the Edit Parameter icon.
	NEXT	Select the Next icon to scroll through the parameters without selecting them. Once a parameter is highlighted, edit the parameter by pressing the Edit Parameter icon.

EDITING A PARAMETER

Once a parameter has been selected for editing, a new set of menu selections and icons are displayed.

	EXIT	Select the Exit icon to exit the parameter without making the new selections permanent.
	ACCEPT	Select the Accept icon to save the changes.
	PREVIOUS	Select the Previous icon to increase or toggle the parameter settings.
	NEXT	Select the Next icon to decrease or toggle the parameter settings.

MENU TREE

This section gives an overview of the menu selections that are available. To navigate through the menus, use the touch key icons and control buttons located on the front panel of the Handheld, to the right of the LCD display. The following sub-sections describe each menu item in more detail.

ALARMS	% SpO_2 high/low limit
	Pulse rate high/low limit (bpm)
	Type of alarm limits
	Silence
	Level

DISPLAY	View
	Contrast
	Language

GENERAL	Averaging Time
	FastSat
	Home Use
	Interface Alarms
	SatShare Numbers
	Power Save

CLOCK	Time (hour/minute)
	Time display format
	Date (day/month/year)
	Date display format

ABOUT	Software Version

OUTPUT	Serial Mode
	Analog Output Mode

SERVICE	Handheld Battery Deep Discharge
	DS Battery Deep Discharge

alarms

Check alarm limits each time the pulse oximeter is used to ensure that they are appropriate for the patient being monitored. An audible alarm and a flashing alarm icon (and indicator light) will occur when an alarm limit is met or exceeded.

MENU ITEMS	DESCRIPTION
SpO_2 HIGH LIMIT	The SpO_2 high alarm limit can be set anywhere between 2% and 100%, with a 1% step size. In the "----" (off) setting, the alarm can be turned off completely.
SpO_2 LOW LIMIT	The SpO_2 low alarm limit can be set anywhere between 1% and 100%, with a 1% step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.*
PULSE RATE HIGH LIMIT (BPM)	The pulse rate high alarm limit can be set anywhere between 30 BPM and 240 BPM, with a 5 BPM step size.
PULSE RATE LOW LIMIT (BPM)	The pulse rate low alarm limit can be set anywhere between 25 BPM and 235 BPM, with a 5 BPM step size. ***NOTE:*** *The low alarm limit always has to be set below the high alarm setting. When the high alarm limit is set below the low alarm limit, the low alarm limit will automatically adjust to the next setting below the newly entered high alarm limit setting.*
TYPE OF LIMITS	The Radical stores three types of alarm limits: Adult, Neo or Custom limits. Adult and Neo limits are preset and cannot be changed by the user. The following table outlines the default values of the preset and custom alarm limits.

TYPES	SpO_2 (HIGH)	SpO_2 (LOW)	PULSE RATE (HIGH)	PULSE RATE (LOW)
ADULT LIMITS	Off	90%	140 BPM	50 BPM
NEO LIMITS	100%	90%	180 BPM	100 BPM
CUSTOM LIMITS	Off*	90%*	140 BPM*	50 BPM*

***NOTE:** The custom limits are set to the values listed in the table at the factory. Once the values are changed, the new values are retained after a power cycle.*

SILENCE	This menu allows the user to set the alarm silence period. An alarm is silenced by pressing the Alarm Silence button on the front panel. **30, 60, 90,120 SECONDS** The alarm silence duration is set. As an indicator that the alarm system is silenced, the Alarm Status Indicator is shown as a bell with a slash through it. A timer is shown next to the bell indicating the remaining alarm silence duration. ***NOTE:*** *The alarm silence period is reset to 120 seconds upon power cycle, except for when the Radical is set to operate in the Home mode.* **ALL MUTE** All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As an indicator that the system is set to All Mute, the Alarm Status Indicator is shown as a flashing bell with a slash through it. **ALL MUTE WITH AUDIBLE REMINDER** All patient alarm conditions are silenced. Only system alarms will be indicated by an audible alarm. As a reminder, a single audible alarm will occur every three minutes. As an indicator that the system is set to All Mute the Alarm Status Indicator is shown as a flashing bell with a slash through it.
LEVEL	This menu allows the user to set the alarm volume. Four levels are available: level 1 being the softest and level 4 being the loudest. The device retains the Alarm Volume setting upon a power cycle. ***NOTE:*** *For home use, set the alarm level to level 4.*

WARNING: IF AN ALARM CONDITION OCCURS WHILE THE ALARM SILENCE PERIOD IS SET TO ALL MUTE, THE ONLY ALARM INDICATIONS WILL BE VISUAL DISPLAYS AND SYMBOLS RELATED TO THE ALARM CONDITION. NO ALARM TONE WILL SOUND.

display

MENU ITEMS	DESCRIPTION
VIEW	Three views are available: Pleth and Signal IQ, Numbers and Pleth Only. **PLETH + SIGNAL IQ** Shows the SpO_2 and pulse rate numbers on the left or top of the screen, and the plethysmograph and Signal IQ waveform on the right or bottom of the screen. The Screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. **PLETH ONLY** Shows the SpO_2 and pulse rate numbers on the left or top of the screen,and the plethysmograph waveform on the right or bottom of the screen. The Screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component. **NUMBERS** Shows the SpO_2 and pulse rate numbers and the signal IQ in the form of a pulse bar on the screen. The Screen also indicates the signal strength of the measured signal as a perfusion index (PI). The PI is calculated as the relation of arterial pulsatile signal to the non-pulsatile signal component.
CONTRAST	Allows the user to set the contrast of the LCD display. Contrast ranges from 1 to 64. ***NOTE:*** *The contrast can also be set by pressing and holding the Backlight/ Contrast Button on the front panel.*
LANGUAGE	Allows the user to select the language displayed on the screen.

general

MENU ITEMS	DESCRIPTION
AVERAGING TIME	The signal averaging time of this device can be set to: 2, 4, 8, 10, 12, 14 and 16 seconds*. *With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging times may range from 2-4 and 4-6 seconds, respectively.
FASTSAT	Select "Yes" to activate the FastSat algorithm. In the 2 and 4 seconds averaging mode, the FastSat algorithm is automatically enabled.
HOME USE	Set the Radical to the Home Mode. The Radical will remain in the Home Mode until the "No" setting is selected. A password is required to activate or deactive this mode. See Section 4, Home Use Operation, for a detailed description.
INTERFACE ALARMS	During SatShare, HP Vuelink and Spacelabs Flexport operation, the audible alarms can be enabled or disabled.
SATSHARE NUMBERS	During SatShare operation the saturation and pulse rate measurements can be displayed on the Radical by selecting a SatShare Numbers setting of "Yes".
POWER SAVE	Select "Yes" to maximize battery-operating time of the Radical while powered by the Handheld battery or optional Docking Station battery. Selecting "Yes" will disable Docking Station functions such as SatShare, Serial and Analog output. Selecting "No" will activate these Docking Station functions while operating on battery power. (While operating in the Power Save mode, a power cycle of the Radical may be required to activate the Docking Station again after it has been disabled.)

clock

MENU ITEMS	DESCRIPTION
TIME	Set the time - hour and minutes - in 12 or 24 hour format.
TIME FORMAT	Set the format of the time display as it will be shown on the front panel. Available options are 12 hour (default) and 24 hour display.
DATE	Set the date (day, month and year).
DATE FORMAT	Set the format of the date display as it will be shown on the front panel. Available options are mm/dd/yyyy (default) and dd/mm/yyyy.

about

This displays the copyright and software versions of the Handheld and Docking Station.

output

Note: *The output menu selections are only available when the Radical Handheld is interfaced to the Docking Station.*

MENU ITEMS	DESCRIPTION
SERIAL MODE	The following serial output modes are supported. All serial output is RS-232 based. See the interface specifications in Section 7, Specifications. **ASCII 1** ASCII text data is sent to the serial interface at one-second intervals. The ASCII text includes: date and time stamp, SpO_2 pulse rate, PI, and alarm and exception values. All text is single line followed by a line feed character and a carriage return. **ASCII 2** ASCII text data is sent to the serial interface following a query from the connecting computer. **HP VUELINK** SpO_2, pulse rate and plethysmographic waveform data are sent in HP VueLink format to the serial port. **SPACELABS FLEXPORT** SpO_2, pulse rate and plethysmographic waveform data are sent in Spacelabs Flexport format to the serial port.
ANALOG OUTPUT MODE	**0%-100%** Scales the saturation measurement with 0% being equal to 0 Volt and 100% equal to 1 Volt. **50%-100%** Scales the saturation measurement with 50% being equal to 0 Volt and 100% equal to 1 Volt. **0V Output** A 0 Volt calibration signal is mapped onto the SpO_2 and pulse rate analog output. Use this signal for calibration of recording devices. (0 Volts represents a saturation of 0% and a pulse rate of 0 bpm).

1V Output

A 1 Volt calibration signal is mapped onto the SpO_2 and pulse rate analog output. Use this signal for calibration of recording devices. (1 Volt represents a saturation of 100% and a pulse rate of 250 bpm).

CAUTION: TO AVOID EXCESSIVE BATTERY DISCHARGING, DO NOT CONNECT ANY EQUIPMENT TO THE SERIAL PORT ON THE BACK PANEL UNLESS THE RADICAL PULSE OXIMETER IS CONNECTED TO THE AC MAIN POWER SUPPLY.

service

NOTE: *The Service menu selections are only available when the Radical Handheld is interfaced to the Docking Station.*

Only qualified Biomedical or Clinical Engineering department personnel should access the service menu. See Section 4, Password Operation, on how to enter the password.

MENU ITEM	DESCRIPTION
HANDHELD BATTERY DISCHARGE:	To deep discharge the Handheld battery select this menu item. See Section 9, Battery Operation and Maintenance, for more information.
DS BATTERY DISCHARGE:	To deep discharge the optional Docking Station battery select this menu item. See Section 9, Battery Operation and Maintenance, for more information.

The discharge cycle will take approximately 16 hours to complete for the Handheld battery. The Docking Station battery will take approximately 30 hours to complete. A message will appear in the service screen when the discharge cycle is complete. The batteries will be fully charged after completion of the cycle.

NOTE: *In order for the discharge cycle to be properly completed, AC power must be supplied to the instrument throughout the cycle.*

WARNING: WHEN DEEP-DISCHARGING THE HANDHELD OR DOCKING STATION BATTERY, MAKE SURE THAT THE DEVICE HAS BEEN REMOVED FROM SERVICE UNTIL FULL BATTERY CAPABILITY CAN BE RESTORED.

trend display

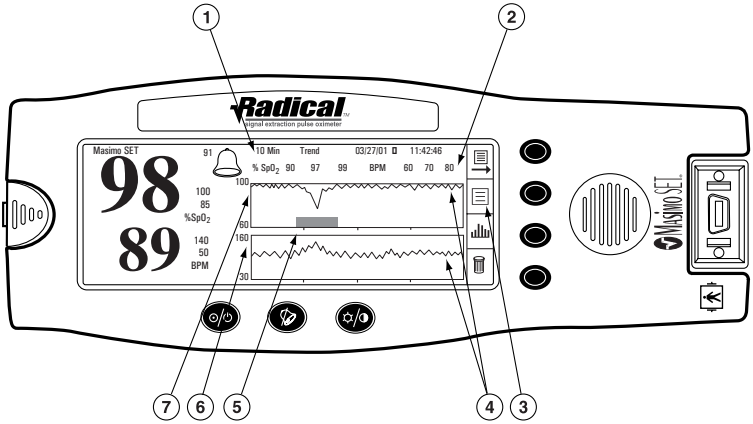
Once the Trend Display touch key icon is selected the trend data is displayed on the main screen. The Radical stores one data set of SpO_2, pulse rate and system messages in a dedicated memory area. Depending on the Trend Period, a setting for how often the data is stored in the trend memory, the Radical can store between 72 hours and 30 days worth of trend data. The Radical also employs a sophisticated data compression scheme. The actual amount of trend data that is stored is dependent on the type of data that is collected.

The Radical only stores data in the trend memory while the device is turned on, and the trend data remains in memory until the memory fills up, or is cleared by the user.

CAUTION: CHANGING THE DATE AND TIME OF THE SYSTEM CLOCK, OR CHANGING THE TREND PERIOD, WILL ALSO CLEAR THE DATA IN THE TREND MEMORY.

The following table outlines the trend capacity for sample Trend Period settings:

TREND PERIOD	TREND MEMORY CAPACITY
2 SECONDS	MINIMUM OF 72 HOURS (3 DAYS)
10 SECONDS	TYPICALLY 720 HOURS (30 DAYS)



① The top line on the trend display shows the time scale of the trend graph, followed by the starting date, starting time and end time of the data set that is displayed on the screen.

② The second line of the display shows the minimum, average, and maximum SpO_2 and pulse rate measurements contained in the displayed data set (excluding zero measurements).

③ The vertical scale of the SpO_2 and pulse rate graphs can be set in the Trend Setup menu.

④ A dark line on the trend graph indicates the averaged data, while grayed-out data points show minimum and maximum values.

⑤ A grayed-out box or line located on the bottom axis of the saturation graph indicates a period of time for which the Low Signal IQ indicator was active, indicating the signal quality was very low and the accuracy of the measurement may have been compromised.

⑥ The second trend graph shows the pulse rate measurements displayed versus time.

⑦ The first trend graph shows the SpO_2 measurements displayed versus time.

By default, the trend display automatically refreshes, at a rate of once every 10 seconds, to show the latest measured SpO_2 and pulse rate data. This feature is only available while the trend view is 2 hours or less, and the latest measured data is shown. If the user scrolls through the data set to display previously recorded trend data, or if the trend scale is greater than 2 hours, the trend display will time out after 1 minute of inactivity (i.e. the user does not press any of the touch key control buttons) and the normal Radical display will be shown.

NAVIGATING THE TREND DISPLAY

In the Trend Display view there are a total of 10 touch key icon selections on 3 pages of menu selections.

FIRST PAGE

Next Menu Page	Press the Next Menu Page button to access the next page of menu selections.
Exit	Press the Exit button to return to the normal display screen.
Scroll Left	Press the Scroll Left button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Left button will scroll the displayed data by 1 hr to the left.
Scroll Right	Press the Scroll Right button to scroll through the data set. The display scrolls by ½ the selected time scale. For example if a 2 hr display view is selected, then pressing the Scroll Right button will scroll the displayed data by 1 hr to the right.

SECOND PAGE

Next Menu Page	Press the Next Menu Page button to access the next page of menu selections.
Zoom	Press the Zoom button to change the time scale of the trend view. The available time scales are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds. The Zoom button uses the last recorded data point as the zoom reference point. In other words, the last recorded data point is always shown as the right-most data point on the display.
Zoom from Left	Press the Zoom from Left button to zoom into the data set while keeping the data point that is shown on the right side of the trend graph as the zoom reference point.
Zoom from Right	Press the Zoom from Right button to zoom into the data set while keeping the data point that is shown on the left side of the trend graph as the zoom reference point.

THIRD PAGE

Next Menu Page	Press the Next Menu Page button to return to the first page of menu selections.
Trend Setup	Press the Trend Setup button to enter the Trend Setup Menu.
Histogram	Press the Histogram button to display the selected data set (the data set shown in the trend view) in histogram format.
Clear Trend Data	Press the clear Trend Data button to clear the data stored in the trend memory.

TREND SETUP

This menu allows the user to set the default trend settings and to clear the trend data, or download the trend data to the serial port. The default settings are used to scale the trend graphs when the trend data button, located on the main display, is accessed.

MENU ITEMS	DESCRIPTION
%SpO_2 HIGH SCALE:	Sets the high scale of the SpO_2 trend graph.
%SpO_2 LOW SCALE:	Sets the lower scale of the SpO_2 trend graph.
PR HIGH SCALE (BPM):	Sets the high scale of the pulse rate trend graph.
PR LOW SCALE (BPM):	Sets the lower scale of the pulse rate trend graph.
DEFAULT VIEW:	Selects the default time scale of the trend view. This setting only selects the time scale of the trend view when the trend data is initially displayed, (i.e. when the trend data is initially accessed). The selections are 24 hrs, 12 hrs, 8 hrs, 4 hrs, 2 hrs, 1 hr, 30 minutes, 10 minutes, 1 minute and 20 seconds.
TREND ACTION	**Serial Dump** To send all the data that is stored in trend memory to the serial port select the Serial Dump option. Use this option to communicate the stored data set to trend graphing software applications. **Analog Dump** To send all the data that is stored in the trend memory to the analog output select the Analog Dump option. Use this option to print the trend information on an analog chart recorder. **Print** To print the trend data that is shown in the Trend View select the Print option. The trend data is first printed in histogram format, followed by a table of data that shows the time and date stamp of a trend record, and the SpO_2 and pulse rate measurement. Each trend record is printed on a single line, followed by a carriage return and line feed character.

TREND PERIOD

The Trend period setting determines how often a set of SpO_2 and pulse rate data points is stored in trend memory. A setting of 2, for example, sets the Radical to store one set of SpO_2 and pulse rate measurements every 2 seconds, resulting in a minimum trend capacity of 72 hours. A setting of 10, for example sets the Radical to store one set of data points every 10 seconds, resulting in a typical trend storage capacity of 30 days.

NOTE: *Since the Radical employs a sophisticated data compression scheme the actual trend capacity is dependent on the type of data that is collected.*

backlight/contrast operation

The backlit LCD screen of the Radical Handheld can be set to four levels of illumination, in addition to no illumination, when Radical operates as a standalone pulse oximeter. The Radical temporarily indicates the illumination level on the display following a change in illumination level. To select the level of illumination simply press the Backlight/Contrast button located on the front panel of the Handheld.

When the Radical Handheld unit is released from the Docking Station the illumination of the LCD screen automatically reverts to the lowest level (backlight off) to conserve battery power. To select a different level of illumination, press the Backlight/Contrast button again. In the Handheld mode, three levels of illumination are available.

When the Handheld unit is re-attached to the Docking Station, as well as when the Radical is powered on in the Standalone configuration, the backlight is automatically set to the maximum illumination when the unit is AC line powered.

To change the contrast of the LCD screen, select the Contrast parameter of the Display menu. While changing the contrast setting, the screen will refresh to reflect the current setting.

The contrast of the LCD screen can also be changed by depressing and holding the Backlight/Contrast button located on the front panel of the Handheld. While holding the Backlight/Contrast button, the screen will refresh to reflect the current setting. Release the button at the desired setting.

satshare operation

When the SatShare cable is connected to the Radical and to a multiparameter patient monitor, the Radical automatically starts to operate in the SatShare mode.

In the SatShare mode, Radical operates as follows:

- All visual alarms remain active.
- All audible alarms may be disabled by software configuration of the Radical.
- The SpO_2 and pulse rate numbers may or may not be displayed on the Radical display depending on the SatShare Numbers setting of the General menu.
- All other items are displayed, including the alarm limits, the plethysmogram and Signal IQ waveform.

- The user can access the menu system.
- If the SatShare cable is connected to the Radical only, and not to a patient monitor, the SatShare cable type is flashing on the LCD screen.
- Once Radical detects the presence of a patient monitor, the SatShare cable type remains constantly displayed on the LCD screen.
- Patient Alarms of the multiparameter patient monitor will be triggered by the alarm setting of the patient monitor and not the Radical. To synchronize the alarm events set the alarm limits of the Radical to those of the patient monitor, or vice versa.
- Once Radical detects that the SatShare cable is disconnected from the patient monitor, or if the patient monitor is turned off, Radical automatically returns to normal, standalone operation.
- In the SatShare mode, the pulse beep tone of the Radical is disabled.
- The Radical may automatically set the averaging time during SatShare operation. For averaging times of 10 seconds and higher, the Radical will automatically set the averaging time to 8 seconds during SatShare operation. Averaging times of 2, 4 or 8 seconds remain unchanged during SatShare operation. When the Radical returns to non-SatShare operation, the Radical will maintain the averaging time setting used in the SatShare mode.

CAUTIONS:

- SATSHARE SIGNALS ARE IDEAL SIMULATED WAVEFORMS CORRESPONDING TO THE CALCULATED SATURATION AND PULSE RATE VALUES AND DO NOT CONTAIN ALL OF THE INFORMATION CONTAINED IN PHYSIOLOGICAL WAVEFORMS. THE MULTIPARAMETER PATIENT MONITOR DECODES THESE SIGNALS INTO SATURATION AND PULSE RATE VALUES.
- DURING SATSHARE OPERATION, THE AUDIBLE PATIENT ALARMS MAY BE AUTOMATICALLY DISABLED AND SILENCED. USE THE MULTIPARAMETER PATIENT MONITOR ALARMS TO INDICATE ALARM CONDITIONS.
- DURING SATSHARE OPERATION DO NOT USE THE PLETH WAVEFORM DISPLAY ON THE MULTIPARAMETER MONITOR FOR DIAGNOSTIC PURPOSES. INSTEAD, USE THE PLETH WAVEFORM DISPLAYED ON THE RADICAL SCREEN.

To return from SatShare operation to normal standalone operation, simply disconnect the SatShare cable from the patient monitor or disconnect the SatShare cable from the SatShare connector on the back of the Radical.

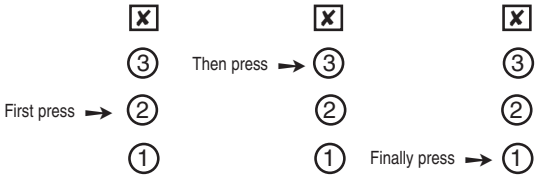
home mode operation

The Radical can be placed into the Home Mode to protect unqualified users from changing the Radical alarm settings and operation. Entering a password does not automatically reset the Radical to the Normal operating mode. In the Home Mode, a password is required to access the menu system and the touch key control buttons and icons.

NOTE: *When the Radical is set to operate in the Home mode the default values that the Radical reverts to after a power cycle are set according to Section 3, Monitor Setup, with the exception of the Alarm Silence setting, which is set to the pre-power down setting.*

password operation

The Radical password is 2-3-1. To enter the password use the touch-key control buttons to the right or bottom of the LCD display and press the buttons in the sequence shown in the following figure:



To return to normal operating mode set the General/Home Use parameters to “No”.

introduction

The following sections outline system alarms, messages displayed on the LCD screen.

Please become thoroughly familiar with this information before operating the pulse oximeter.

alarm identification

The Radical Pulse Oximeter visually and audibly indicates alarm conditions that the system detects. The integrated loudspeaker indicates alarm conditions audibly. The LCD screen and the LED lights on the Docking Station indicate the visual alarms. Audible alarms may be silenced, without affecting the operation of visual alarms.

Two levels of alarm priority are implemented: high and low priority. The following table outlines the alarm priority specifications.

ALARM	DESCRIPTION
HIGH PRIORITY	Audible and visual alarms for high and low saturation (SpO_2 range 1-100%) and pulse rate (pulse rate range 25-240 bpm). Audible and visual alarms for system failures. Sensor Failure and Disconnect.
LOW PRIORITY	Audible and visual alarms for low battery.

NOTE: *High priority alarms indicate that immediate operator response is required. Low priority alarms indicate that operator awareness is required.*

alarm operation

For averaging modes of less than 14 seconds, the Radical indicates saturation and pulse rate alarms within 3 seconds of when the alarm condition is met. For averaging modes of 14 and 16 seconds, the Radical indicates saturation and pulse rate alarms within 10 seconds of when the alarm condition is met. Saturation changes of greater than 5% are indicated immediately, irrespective of averaging time. The Radical visually indicates an alarm by flashing the measured value and the alarm limits. Alarms are audibly indicated according to system configuration.

alarm messages

Alarm messages indicate a problem or condition, which may affect accurate monitoring values. Do not ignore these messages. Correct any fault before continuing.

Press the Alarm Silence key to temporarily silence the audible alarm. Alarm messages and violating values flash on the display, and the Docking Station front panel alarm indicator flashes red if the Handheld unit is in the Docking Station. If the measurement returns to within limits, the alarm turns off.

A list of alarm conditions that cause audible and visual alarm indications and the displayed alarm messages are shown in the following table. The reason of why these alarms might occur is also shown.

MESSAGE	DESCRIPTION
SENSOR OFF	*The sensor is not properly attached to the patient.*
NO SENSOR	*The sensor is not properly attached to the monitor.*
SpO_2 HIGH	*The high SpO_2 rate limit has been exceeded.*
SpO_2 LOW	*The low SpO_2 rate limit has been exceeded..*
PR HIGH	*The high pulse rate limit has been exceeded.*
PR LOW	*The low pulse rate limit has been exceeded.*

system messages

The following chart alphabetically lists all system messages displayed on the LCD screen. The cause of the message, and the action(s) to be taken are also shown.

The operator should become thoroughly familiar with this information before using the oximeter for patient monitoring.

MESSAGE	POSSIBLE CAUSE(S)	RECOMMENDATION
AMBIENT LIGHT	Too much light on patient (sensor). Inadequate tissue covering sensor detector.	Remove or reduce lighting. Cover sensor from light. Reposition sensor.
DEFECTIVE SENSOR	Oximeter cannot identify the connected sensor the sensor has failed.	Broken sensor cable wire or inoperative LEDs or faulty detector; Replace sensor. Refer to the instructions for the sensor being used.
INTERFERENCE	Outside signal or energy preventing reading.	Remove outside interference.
INVALID SENSOR	Oximeter cannot identify the connected sensor	Broken sensor cable wire or inoperative LEDs or faulty detector; the sensor has failed. Replace sensor. Refer to the instructions for the sensor being used.
LOW BATTERY	Battery charge is low.	Charge battery by placing the Radical Handheld into the Docking Station and powering the unit with AC line power. Replace battery if necessary.
LOW PERFUSION	Signal too small.	Move sensor to better perfused site. Refer to Section 4, Low Perfusion.
LOW SIGNAL IQ	Low signal quality.	Ensure proper sensor application. Move sensor to a better perfused site. Refer to Section 4, Signal IQ.

NO SENSOR	Sensor not fully inserted into the connector. Sensor inserted upside down.	May be an incorrect sensor, or a defective sensor or cable. Insert sensor into connector. Disconnect and reconnect sensor. Refer to the instructions for the sensor being used. Disconnect and reconnect the sensor with the logos matching.
PULSE SEARCH	Unit is searching for patient's pulse.	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If pulse search continues, remove sensor and replace on a better perfused site.
SENSOR OFF	Sensor off patient.	Disconnect and reconnect sensor. Reattach sensor.
SERVICE * REQUIRED	Internal Failure.	Unit requires service.

* The SERVICE REQUIRED message fills the entire display.

troubleshooting

The following chart describes what to do if the Radical system does not operate properly or fails.

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
UNIT DOES NOT POWER ON.	One or both of the fuses have blown.	Replace the fuses.
UNIT POWERS ON BUT THE GRAPHIC DISPLAY IS BLANK.	The viewing contrast is not correct.	Use the Backlight/Contrast button to adjust the viewing angle. If the condition persists, the unit requires service.
CONTINUOUS SPEAKER TONE.	Internal failure.	Unit requires service. Press the Alarm Silence button to silence the alarm. If alarm continues to sound, power down unit and remove Handheld battery if necessary.
BUTTONS DON'T WORK WHEN PRESSED	Internal failure.	Unit requires service.

The following chart describes what to do when encountering common problems:

PROBLEM	POSSIBLE CAUSE(S)	RECOMMENDATION
HANDHELD BATTERY DOES NOT CHARGE.	AC power cable may be disconnected. AC power switch is turned off.	Restore power to the device.
PRINT FUNCTION DOES NOT WORK.	Wrong serial cable is used.	Make sure a null modem cable is used.

radical specifications

PERFORMANCE

measurement range	
SpO_2:	1-100%
Pulse Rate:	25-240 beats per minute (bpm)
Perfusion:	0.02% - 20%

accuracy	
Saturation	70% to 100%
No Motion[1]	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Motion	
Adults[2] , Pediatrics[2]	±3 digits
Neonate[3]	±3 digits
Low Perfusion[4]	
Adults, Pediatrics	±2 digits
Neonate	±3 digits
Pulse Rate Accuracy	
pulse rate:	25-240 bpm
No Motion[1]	
Adults, Pediatrics, Neonate	±3 digits
Motion[2,3]	
Adults, Pediatrics, Neonate	±5 digits
Low Perfusion[4]	
Adults, Pediatrics, Neonate	±3 digits

resolution	
Saturation (%SpO_2)	1%
Pulse Rate (bpm)	1 bpm

ELECTRICAL

standalone	
AC Power requirements:	100-240 VAC, 47-63 Hz
Power consumption:	55 VA
Fuses:	1 Amp, Fast Acting, Metric, (5x20mm), 250V

batteries	
Handheld:	
Type:	NiMH
Capacity:	4 hours[5]
Charging time:	3 hours
Docking Station (RDS-1B, RDS-3B):	
Type:	NiMH
Capacity:	12 hours[5]
Charging time:	6 hours

ENVIRONMENTAL

Operating Temperature:	41°F to 104°F (5°C to 40°C)
Storage Temperature:	-40°F to 158°F (-40°C to +70°C)[6]
Operating Humidity:	5% to 95%, non-condensing
Operating Altitude:	1060 mbar to 500 mbar pressure, -1000 ft to 18,000 ft (-304 m to 5,486 m)

PHYSICAL CHARACTERISTICS

dimensions

Handheld:	8.9" x 3.3" x 2.1" (22.6 cm x 8.4cm x 5.3 cm)
Standalone:	3.5" x 10.5" x 7.7" (8.9 cm x 26.7cm x 19.6cm)

weight

Handheld:	1.3 lbs. (0.59 kg)
Docking Station (RDS-1, RDS-2, RDS-3):	2.5 lbs. (1.14 kg)
Docking Station (RD-1B, RDS-3B):	4.11 lbs (1.86 kg)
Standalone (RDS-1, RDS-2, RDS-3):	3.8 lbs. (1.73 kg)
Standalone (RDS-1B, RDS-3B):	5.4 lbs. (2.45 kg)

trending

72 hours of trending at 2 second resolution, up to 30 days of trending at 10 second resolution , output to serial printer or other serial devices

modes

Averaging mode:	2, 4, 8,10, 12, 14 or 16 seconds[7]
Sensitivity:	Normal and Maximum[8]

alarms

Audible and visual alarms for high low saturation and pulse rate (SpO_2 range 1-100%, pulse rate range 25-240 bpm)

Sensor condition, system failure and low battery alarms

High Priority:	571 Hz tone, 5 pulse burst, pulse spacing: 0.250s, 0.250s, 0.500s, 0.250s, repeat time:10s
Low Priority:	500Hz tone, 1 pulse, repeat time: 5s
Alarm Muted reminder:	500Hz tone, 2 pulse burst, pulse spacing 0.375s, repeat time: 3min.

display/Indicators

Data display: %SpO_2, pulse rate, pleth waveform, alarm status, trends, status messages, Signal IQ and perfusion index

Type:	Backlit LCD
Pixels:	480 x 160 dots
Dot Pitch:	0.25 mm

output interface

SatShare (RDS-1, RDS-1B),

Serial RS-232, Analog Output, Nurse Call (RDS-1, RDS-1B, RDS-3, RDS-3B)

HP Vuelink, Spacelabs Universal Flexport (RDS-1, RDS-1B, RDS-3, RDS-3B)

compliance	
EMC Compliance:	EN60601-1-2, Class B
Equipment Classification:	IEC 60601-1-1 / UL 2601-1

Type of Protection:	Class 1 (on AC power), Internally powered (on battery power)
Degree of Protection-Patient Cable:	Type BF-Applied Part
Degree of Protection-SatShare Cable:	Type CF-Applied Part
Enclosed Degree of Ingress Protection from Solids/Liquids:	IPX1
Mode of Operation:	Continuous

[1] The Masimo SET Radical Pulse Oximeter with LNOP Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET Radical Pulse Oximeter with LNOP Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3] The Masimo SET Radical Pulse Oximeter with LNOP Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Pulse or minus one standard deviation encompasses 68% of the population.

[4] The Masimo SET Radical Pulse Oximeter with SatShare has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[5] This represents approximate run time with no backlight and Power Save mode, using a new, fully charged battery.

[6] If the batteries are to be stored for extended periods of time, it is recommended that they be stored between -20°C to +30°C, and at a relative humidity less than 85%. If stored for a prolonged period at environmental conditions beyond these limits, overall battery capacity may be diminished, and lifetime of the batteries may be shortened.

[7] With FastSat the averaging time is dependent on the input signal. For the 2 and 4 second settings the averaging time may range from 2-4 and 4-6 seconds, respectively.

[8] Maximum sensitivity mode fixes perfusion limit to 0.02%.

serial interface specifications

The digital interface for serial communication is based on the standard RS-232 protocol.

The Radical Pulse Oximeter by default always outputs ASCII1 text data through the serial port, unless the user selects a different output mode in the Output menu. To interface with the Radical and receive serial text data, simply connect a serial interface cable to the serial output connector located on the back of the Radical Docking Station.

NOTE: *The Radical serial interface is only available when the Radical Handheld is properly attached to the Radical Docking Station.*
NOTE: *The serial interface is not available in all versions of the docking station.*

Once serial communication is established, packets of data are communicated at 1 second intervals. The data packets contain: the date, time, SpO_2, pulse rate, perfusion index and alarm and exception values. (in ASCII format).

WARNING: ALL EXTERNAL DEVICE CONNECTIONS TO THE ANALOG OUTPUT/ NURSE CALL CONNECTOR MUST BE IEC-60950 COMPLIANT.

SERIAL INTERFACE SETUP:
To interface with the Radical serial port, set the following communication parameters on the interfacing serial device:

PARAMETER	SETTING
BAUD RATE	9600 Baud bi-directional
NUMBER OF BITS PER CHARACTER	8
PARITY	None
BITS	1 start, 1 stop
HANDSHAKING	None
CONNECTOR TYPE	Female DB-9

The pin-outs for the RS-232 connector are shown in the following table:

PIN	SIGNAL NAME
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM signals
6	No Connection
7	No Connection
8	No Connection
9	No Connection

SERIAL PRINTER SETUP
To print the SpO_2 and pulse rate data in ASCII1 format on a serial printer, simply connect the laser printer to the serial port. Once serial communication is established, the Radical automatically will start printing the ASCII1 text data.

analog output / nurse call specifications

The Analog Out and Nurse Call are features accessible on the same female high density DB-15 connector.

NOTE: *The Radical analog output / nurse call interface is only available when the Radical Handheld is properly attached to the Radical Docking Station.*

NOTE: *The analog output/nurse call interface is no available in all version of the Docking Station.*

WARNING: ALL EXTERNAL DEVICE CONNECTIONS TO THE RS-232 SERIAL PORT MUST BE IEC-60950 COMPLIANT.

The following table shows the pinout of the analog output and nurse call.

PIN	SIGNAL NAME
1	+5V (60mA max.)
2	Ground
3	Ground
4	Ground
5	Ground
6	Nurse Call (Normally Open)
7	Nurse Call (Normally Closed)
8	Ground
9	Analog Out - %SpO_2
10	Ground
11	Ground
12	Nurse Call – Common
13	Ground
14	Ground
15	Analog Out – Pulse Rate

ANALOG OUTPUT

Radical can interface with various analog recording devices and/or strip chart recorders through its Analog Output connector located on the back of the Docking Station. SpO_2 and pulse rate parameters are output simultaneously and continuously. The output signals vary from approximately 0 to 1 volt in a linear fashion.

NOTE: *The actual SpO_2 and Pulse Rate voltages will vary from approximately 40mV to 980mV in 3.9mV steps.*

SpO_2

0 volts represents either 0% SpO_2 or 50% SpO_2. In either case, 1 volt is used to represent 100% SpO_2. The range mapping for %SpO_2 can be selected by accessing the menu system under Output-Analog Output Mode.

PULSE RATE

For Pulse Rate, 0 volts represents 0 BPM, while 1volt is used to represent 250 BPM.

CALIBRATION

For measurement device calibration purposes, the analog output signals can be set to either 0 volts or 1 volt in the menu system under Output/Analog Output Mode. These settings affect both channels. Calibrate your analog recording system to those levels before use.

NURSE CALL

The nurse call feature is available when Radical is operating in its standalone configuration. The nurse call feature on the Radical Pulse Oximeter is based on the relay closing or opening depending on alarm events. For maximum flexibility, either normally open (pin 6) or normally closed (pin 7) signals are available. Only qualified personnel should connect one of these two signals and common (pin 12) to a hospital's nurse call system. During an alarm condition, the normally open pin will be connected to the common pin and the normally closed will be disconnected.

The nurse call relays have the following electrical specifications per switch:

PARAMETER	SPECIFICATION
Max Voltage	100VDC or AC_{peak}
Max Current	100mA

WARNING: THE NURSE CALL FEATURE IS DISABLED WHEN THE AUDIBLE ALARMS ARE SILENCED.

introduction

This section covers the use and cleaning of Masimo LNOP sensors and Masimo SET patient cables.

masimo LNOP® sensors

Before use, carefully read the LNOP sensor Directions for Use.

Use only Masimo oximetry sensors for SpO_2 measurements. Other oxygen transducers or sensors may cause improper Radical Pulse Oximeter performance.

Tissue damage can be caused by incorrect application or use of an LNOP sensor, for example by wrapping the sensor too tightly. Inspect the sensor site as directed in the sensor Directions for Use to ensure skin integrity and correct positioning and adhesion of the sensor.

CAUTIONS:

- DO NOT USE DAMAGED LNOP SENSORS. DO NOT USE AN LNOP SENSOR WITH EXPOSED OPTICAL OR ELECTRICAL COMPONENTS. DO NOT IMMERSE THE SENSOR IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE SENSORS AND CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO LNOP SENSORS.
- DO NOT USE DAMAGED PATIENT CABLES. DO NOT IMMERSE THE PATIENT CABLES IN WATER, SOLVENTS, OR CLEANING SOLUTIONS (THE PATIENT CABLE CONNECTORS ARE NOT WATERPROOF). DO NOT STERILIZE BY IRRADIATION, STEAM, OR ETHYLENE OXIDE.

SELECTING A MASIMO LNOP SENSOR

When selecting a sensor, consider, the patient's weight, the adequacy of perfusion, the available sensor sites, and the duration of monitoring. For more information refer to the following table or contact your Sales Representative. Use only Masimo SET sensors and sensor cables. Select an appropriate sensor, apply it as directed, and observe all warnings and cautions presented in the directions for use accompanying the sensor.

High ambient light sources such as surgical lights (especially those with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, and direct sunlight can interfere with the performance of an SpO_2 sensor. To prevent interference from ambient light, ensure that the sensor is properly applied, and cover the sensor site with opaque material, if required. Failure to take this precaution in high ambient light conditions may result in inaccurate measurements.

SENSOR	USAGE	PATIENT WEIGHT
LNOP ADT	Single Use	Adults > 30 kg
LNOP PDT	Single Use	Pediatrics and Slender Adults >10 kg and < 50 kg
LNOP NEO	Single Use	Neonate < 10 kg
LNOP NEO PT	Single Use	Neonate < 1 kg, or with poor skin integrity
LNOP DCI	Reusable	Adults and Pediatrics > 30 kg
LNOP DCIP	Reusable	Pediatrics >10 kg and <50 kg
LNOP DCSC	Reusable	Adult and Pediatrics >30 kg, for spot check applications

CLEANING AND REUSE OF MASIMO LNOP SENSORS

Reusable sensors can be cleaned per the following procedure:

- Remove the sensor from the patient.
- Disconnect the sensor from the monitor.
- Wipe the entire sensor clean with a 70% isopropyl alcohol pad.
- Allow the sensor to air dry before returning it to operation.

REATTACHMENT OF SINGLE USE ADHESIVE SENSORS

- LNOP single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.
- The adhesive can be partially rejuvenated by wiping with a 70% isopropyl alcohol wipe and allowing the sensor to thoroughly air dry prior to replacement on the patient.

NOTE: *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

WARNING: TO AVOID CROSS CONTAMINATION ONLY USE MASIMO LNOP SINGLE USE SENSORS ON THE SAME PATIENT.

CAUTIONS:

- DO NOT REPROCESS ANY LNOP SINGLE USE SENSORS.
- DO NOT SOAK OR IMMERSE THE SENSOR IN ANY LIQUID SOLUTION. DO NOT STERILIZE ANY MASIMO SENSOR BY IRRADIATION, STEAM, OR ETHYLENE OXIDE.

masimo SET patient cables

Reusable patient cables of various lengths are available. All cables that display the Masimo SET logo are designed to work with any Masimo LNOP sensor and with any pulse oximeter or multiparameter instrument displaying the Masimo SET logo.

Only use Masimo oximetry patient cables for SpO_2 measurements. Other patient cables may cause improper Radical pulse oximeter performance.

CLEANING AND REUSE OF MASIMO SET PATIENT CABLES
Patient cables can be cleaned per the following procedure:

- Remove the cable from the sensor.
- Disconnect the cable from the monitor.
- Wipe clean with a 70% isopropyl alcohol pad.
- Allow the cable to dry before returning it to operation.

CAUTIONS:

- CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.
- DO NOT SOAK OR IMMERSE PATIENT CABLES IN ANY LIQUID SOLUTION. DO NOT STERILIZE PATIENT CABLES BY IRRADIATION, STEAM, OR ETHYLENE OXIDE. SEE THE CLEANING INSTRUCTIONS IN THE DIRECTIONS FOR USE FOR REUSABLE MASIMO PATIENT CABLES.
- DO NOT REPROCESS ANY MASIMO SET PATIENT CABLES.

introduction

This chapter covers how to test the operation of the Radical and the SatShare interface, how to properly clean the Radical pulse oximeter, how to recharge and replace the batteries, how to replace the fuses, and how to obtain service.

Under normal operation, no internal adjustment or recalibration is required. Safety tests and internal adjustments should be done by qualified personnel only. Safety checks should be performed at regular intervals or in accordance with local and governmental regulations.

WARNING: ELECTRICAL SHOCK AND FLAMMABILITY HAZARD - BEFORE CLEANING THE OXIMETER, ALWAYS TURN IT OFF AND DISCONNECT THE POWER CORD FROM THE AC POWER SUPPLY.

cleaning

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the instrument.

CAUTIONS:

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THIS OXIMETER.
- DO NOT SOAK OR IMMERSE THE MONITOR IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE MONITOR AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE OXIMETER. THESE SUBSTANCES ATTACK THE DEVICE'S MATERIALS AND DEVICE FAILURE CAN RESULT.

Refer to Section 8, Cleaning and Reuse of Masimo LNOP Sensors for cleaning instructions of the sensor.

battery operation and maintenance

The Radical Handheld includes a 1.5 Amp-Hour Nickel Metal Hydride battery. The Radical Docking Station may include the optional 6.5 Amp-Hour Nickel Metal Hydride battery.

Before using the Radical as a Handheld or transport monitor, the Handheld battery and the optional Docking Station battery need to be fully charged.

To charge the battery(s), attach the Handheld unit to the Docking Station. Ensure that AC power is attached to the Docking Station. Turn the AC power switch to the " I " position. Verify that the battery(s) are charging; the battery charging LED indicators on the Docking Station flash prior to charging and remain illuminated while the battery(s) are charging. A continuously flashing battery charging LED indicates that the internal battery temperature exceeds recommended operating conditions for proper battery charging. Proper battery charging will proceed when the temperature returns to recommended operating conditions.

The Handheld battery requires approximately 2 to 3 hours for charging. The optional Docking Station battery requires approximately 6 hours for charging.

When the battery charging LED indicators turn off, additional trickle charging may occur to complete charging. Although battery charging can occur while the Handheld is docked and powered on, most efficient charge times are achieved with the Handheld unit turned off.

CAUTIONS:

- ALL BATTERIES LOSE CAPACITY WITH AGE, THUS THE AMOUNT OF RUN TIME LEFT AT LOW BATTERY WILL VARY DEPENDING UPON THE AGE OF THE BATTERY.
- AT LOW BATTERY CONNECT THE RADICAL TO AC POWER TO PREVENT LOSS OF POWER.

During battery operation of the Radical, please note that the following operating conditions affect the estimated run-time of the included batteries:

- Illumination of the backlit LCD screen. To conserve battery power, keep the backlit LCD screen at minimum illumination.
- Volume of the alarm tones. To conserve battery power, keep the frequency of the audible alarms to a minimum and at minimum volume.
- The SatShare feature. To conserve battery power, always keep the unit on AC line power.

Memory effects of the batteries may shorten run-time of the batteries. As a precaution against memory effects, it is advisable to completely discharge and fully recharge the batteries at least once every six (6) months. To properly discharge the batteries, use the Battery Discharge function, as described in Section 4, Service.

CAUTION:

- IF THE RADICAL HAS NOT BEEN CHARGED FOR 1 MONTH OR MORE, THEN RECHARGE THE BATTERY PRIOR TO USE.

The following tables outline the estimated run times of the battery powered Radical Pulse Oximeter. The time estimates are based on a Radical with fully charged batteries. The time estimates are also based on a Radical with and without backlight lit, and the power save feature enabled and disabled.

The Radical Pulse Oximeter is always configured to include the Handheld battery. It may optionally be configured to include the Docking Station battery. Please determine the configuration of your system before referencing the following tables.

Configuration #1:

Radical configured to only include the Handheld battery (standard configuration); the Docking Station battery is excluded.

NOTE: *For this configuration, it is advisable to operate only the Radical Handheld unit when running on battery power. Although it is possible to operate the entire Standalone unit (the Handheld attached to the Docking Station, with the Handheld battery powering the Docking Station as well) on battery power, the capacity of the Handheld battery pack is insufficient to support this mode for long periods of time. The Power Save setting in the General menu determines whether the Docking Station is powered or not during battery operation. See Section 4, General, for a detailed description on proper use of the Power Save setting.*

RADICAL CONFIGURATION	OPERATION MODE	RUN-TIME
HANDHELD ONLY	Power Save "yes" Backlight turned "off"	3 to 4 hrs
STANDALONE	Power Save "no" Backlight turned "on"	1 hr

Configuration #2:

Radical configured to include the Handheld and the Docking Station battery:

RADICAL CONFIGURATION	OPERATION MODE	RUN-TIME
STANDALONE	Power Save "yes" Backlight turned "off"	12 hrs
STANDALONE	Power Save "no" Backlight turned "on"	6 to 7 hrs

WARNING: THE DOCKING STATION BATTERY SHOULD BE INSTALLED AND/OR REMOVED FROM DOCKING STATION BY QUALIFIED PERSONNEL ONLY.

REPLACING THE BATTERIES

- Before installing or removing the battery, make sure the AC power cord is removed and power to the pulse oximeter is turned off.

To replace the Handheld battery, follow these instructions:

- Turn the Radical Handheld off and remove the patient cable connection. Detach the Radical Handheld from the Docking Station (if docked).
- Loosen the closure screw on the battery compartment door and lift off the battery compartment door cover.
- Pull out the battery.
- Take a new battery, and place it in the compartment.
- Replace the battery door and tighten the closure screw.
- Place Handheld into Docking Station, turn on line power and charge battery according to Section 9, Battery Operation and Maintenance.

CAUTION: FOLLOW LOCAL GOVERNING GUIDELINES FOR PROPER DISPOSAL OF INTERNAL BATTERIES. DO NOT INCINERATE.

REPLACING THE FUSES

Should a power problem blow one or both of the fuses in the power entry module on the rear panel, the fuse(s) will need to be replaced.

To replace the fuses, you will need a flat-blade screwdriver (5mm; 3/16").

To replace the fuses:

- Disconnect unit from AC power.
- Use the small flat-blade screwdriver and gently pry loose the fuse holder in the right portion of the power entry module.
- Note how the fuses are placed in the fuse holder for installation of the new fuses.
- To remove the fuses from the fuse holder, use the edge of the screwdriver blade to pry against the bottom of the metal portion of the fuse where it is secured to the glass portion of the fuse.
- Place two fuses (1 Amp, Metric, fast acting, 5x20mm, 250V) in the fuse holder, properly orienting the fuses.
- Slide the fuse holder back into the power entry module and press firmly to make sure it is firmly inserted.
- The Unit is ready to be reconnected to AC power.

NOTE: *If the fuses blow shortly after replacement, the unit requires service.*

WARNING: FIRE HAZARD: TO PROTECT AGAINST FIRE HAZARD, REPLACE ONLY WITH FUSES OF THE SAME TYPE, CURRENT RATING, AND VOLTAGE RATING.

performance verification

To test the performance of the Radical pulse oximeter following repairs or during routine maintenance, follow the procedure outlined in this section. If the Radical fails any of the described tests, discontinue its use and correct the problem before returning the unit back to the user.

Before performing the following tests place the Radical Handheld into the Docking Station, connect the Radical to AC power and fully charge the Radical Handheld battery (the AC mains switch must be on). Also disconnect any patient cables or pulse oximetry probes, as well as SatShare, serial or analog output cables from the instrument. Set the Radical to normal operating mode by selecting the Home Use parameter in the General Menu to "No".

Power-On Self-Test:

1. Connect the monitor to AC power and verify that the AC Power Indicator is lit. If it is not lit verify that the AC mains switch is on.
2. Turn the monitor on by depressing the Power/Standby Button. Within 5 seconds all available LEDs are illuminated, a 1-second beep tone sounds, and the Masimo SET logo is displayed.
3. The green Docking Indicator LED is illuminated and the Radical begins normal operation.

Key Press Button Test:

1. With the exception of the Power/Standby Button, press each soft key button and verify that the Radical acknowledges each key-press with an audible beep tone or by indicating a change on the display.

Alarm Limit Test:

1. With the monitor turned on, select the Menu Access key and enter the Alarm menu. Change the High Saturation Alarm parameter to a value two points below the currently selected value, and accept the change.
2. Verify that the newly set parameter is shown on the Saturation Alarm Limit Display, next to the SpO_2 or pulse rate measurement display.
3. Return the High Saturation Alarm parameter to its original setting.
4. Repeat steps 1 to 3 with the Low Saturation Alarm parameter.
5. Repeat steps 1 to 3 with the High Pulse Rate Alarm parameter.
6. Repeat steps 1 to 3 with the Low Pulse Rate Alarm parameter.
7. Reset the alarm limits again to the original settings.

Display Contrast Test:

1. With the monitor turned on, select the Menu Access key and enter the Display menu. Change the Contrast parameter by scrolling through the contrast settings.
2. Return the Contrast setting to the original value, or a value that allows maximum viewing contrast.
3. Exit the Menu system and press and hold down the Backlight/Contrast button for several seconds. The display will scroll again through all the contrast settings.
4. Release the Backlight/Contrast button again when the display shows maximum viewing contrast.

Testing with Masimo SET Tester (Optional):

1. Turn the Radical off and then on again.
2. Set the alarm limits to:

	% SpO_2	Pulse Rate
High	100	140
Low	90	50

3. Connect the Masimo SET Tester to the Patient Cable Connecter.
4. Verify that within 20 seconds a plethysmographic and a Signal IQ waveform displays. (may require the Radical to be set to the Pleth and Signal IQ display setting).
5. Verify that the SpO_2 measurement is between 79% and 84%.
6. Verify that the pulse rate measurement is between 55 bpm and 65 bpm.
7. Verify that an audible alarm occurs and that the SpO_2 measurement and the low SpO_2 alarm are flashing
8. Press the Alarm Silence button once and verify that the alarm is silenced.
9. Wait 120 seconds and verify that the alarm silence times out and the audible alarm is activated again.
10. Press the Increase Loudness button several times and verify that the loudness of the pulse beep tone increases.
11. Press the Decrease Loudness button and verify that the loudness of the pulse beep tone decreases. Press the Decrease Loudness button and verify that the loudness of the pulse beep tone can be turned off.

Nurse Call Test:

1. Disconnect the patient cable or the Masimo SET Tester from the Radical and turn the instrument on. Ensure that there are no audible alarms and that the audible alarms are not silenced.
2. Connect the common lead of a digital multi-meter to the pin 12 (Nurse Call - Common) of the analog output connector on the Radical. Connect the positive lead of the multi-meter to pin 6 (Nurse Call - Normally Open) of the analog output connector and measure that the resistance is greater than 1 MΩ (open circuit).
3. Trigger an alarm on the monitor (e.g. by disconnecting a sensor after it was measuring data) and verify that the resistance is less than 35 ohms.

Analog Output Test

1. Disconnect all patient cables and sensors from the Radical. Turn the Radical off and then on again.

2. Connect the common lead of a digital voltmeter to the pin 2 (Ground) of the analog output connector on the Radical. Connect the positive lead of the voltmeter to pin 9 (Analog Out - % SpO_2) of the analog output connector.

3. Enter the menu system and set the "Output", "Analog Output Mode" to "0V Signal". Verify that the voltmeter measures a voltage of approximately 40mV.

4. Enter the menu system and set the "Output", "Analog Output Mode" to "1V Signal". Verify that the voltmeter measures a voltage of approximately 980mV.

5. Repeat Steps 2 and 3, with the positive lead of the voltmeter connected to pin 15 (Analog Out - Pulse Rate).

6. Connect a patient cable and sensor and verify that the voltage on pins 9 and 15 are between 0V and 1V while measuring a saturation and pulse rate..

Battery Test

1. Fully charge the Radical pulse oximeter by placing the Handheld into the Docking Station and connecting the AC power (the AC mains switch must be on).

2. Verify that the green Handheld Battery Indicator LED is lit up.

3. When the Radical is fully charged the green Handheld Battery Indicator turns off.

4. Turn the Radical on and verify that the Battery indicator shows a full charge.

service and repair

REPAIR POLICY

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the unit repaired.

> **WARNING:** DO NOT REMOVE THE COVER OF THE MONITOR EXCEPT FOR BATTERY REPLACEMENT. AN OPERATOR MAY ONLY PERFORM MAINTENANCE PROCEDURES SPECIFICALLY DESCRIBED IN THIS MANUAL. REFER SERVICING TO QUALIFIED SERVICE PERSONNEL TRAINED IN THE REPAIR OF THIS EQUIPMENT.

Please clean contaminated/dirty equipment before returning, following the cleaning procedure described in Section 9, Cleaning. Make sure it is fully dry before packing the equipment.

To return the Radical unit for service, please follow the Return Procedure.

RETURN PROCEDURE

Please clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Package the equipment securely – in the original shipping container if possible – and enclose the following information and items:

- Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number.
- A letter describing in detail any difficulties experienced with the pulse oximeter. Please include the RMA number in the letter.
- Warranty information – a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the oximeter is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the oximeter has been decontaminated for bloodborne pathogens.

Return Radical pulse oximeter to the following shipping address:

Masimo Corporation
2852 Kelvin Ave
Irvine, California 92614
949-250-9688
FAX 949-250-9686

warranty

Masimo warrants to the initial purchaser that each new pulse oximeter will be free from defects in workmanship or materials for a period of three (3) years from the date of purchase. Masimo's sole obligation under this warranty is to repair or replace any product that Masimo deems to be covered under warranty with a repaired or a replacement pulse oximeter.

To request a replacement under warranty, contact the licensed manufacturer or Masimo for a returned goods authorization. If the licensed manufacturer or Masimo determines that a product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs shall be the responsibility of the purchaser.

exclusions

This warranty does not extend to any product that has been subject to misuse, neglect or accident; that has been damaged by causes external to the Product; that has been used in violation of the operating instructions supplied with the product. The warranty does not extend to any product that has been connected to an unlicensed instrument system, modified accessories or any unit that has been disassembled or reassembled by anyone but an authorized Masimo agent.

THIS WARRANTY, TOGETHER WITH ANY OTHER EXPRESS WRITTEN WARRANTY THAT MAY BE ISSUED BY MASIMO IS THE SOLE AND EXCLUSIVE WARRANTY AS TO MASIMO'S PRODUCTS. THIS WARRANTY IS EXPRESSLY IN LIEU OF ANY ORAL OR IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. MASIMO SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE DIRECTLY OR INDIRECTLY ARISING FROM THE USE OR LOSS OF USE OF ANY PRODUCTS.

accessories

The following accessories and re-order parts are available with the Radical Signal Extraction pulse oximeter:

ACCESSORIES	PART NUMBER
RADICAL HANDHELD	1309
RADICAL DOCKING STATION RDS-1	1310
RADICAL DOCKING STATION RDS-1B	1311
RADICAL DOCKING STATION RDS-2	1392
RADICAL HANDHELD LOCK	1395
REPLACEMENT BATTERY RADICAL - HANDHELD	1315
POLE CLAMP	1317
OPERATOR'S MANUAL - ENGLISH	11601
OPERATOR'S MANUAL - GERMAN	11714
OPERATOR'S MANUAL - FRENCH	11715
OPERATOR'S MANUAL - ITALIAN	11716
OPERATOR'S MANUAL - PORTUGUESE	11717
OPERATOR'S MANUAL - SPANISH	11718
OPERATOR'S MANUAL - DUTCH	11901
OPERATOR'S MANUAL - DANISH	11902
OPERATOR'S MANUAL - SWEDISH	11903

ACCESSORIES	PART NUMBER
SATSHARE CABLE-DO01	1324
SATSHARE CABLE-DO02	1326
SATSHARE CABLE-DO03	1528
SATSHARE CABLE-DO04	1533
SATSHARE CABLE-DS01	1325
SATSHARE CABLE-DS02	1539
SATSHARE CABLE-HP01	1320
SATSHARE CABLE-MQ01	1321
SATSHARE CABLE-NK01	1367
SATSHARE CABLE-OH01	1366
SATSHARE CABLE-SL01	1323
SATSHARE CABLE-SL02	1362
SATSHARE CABLE-SM01	1322

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